572-B

code of federal regulations

Animals and Animal Products

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9

PARTS 1 TO 199
Revised as of January 1, 1986

DP

code of federal regulations

Animals and Animal Products

9

PARTS 1 to 199

Revised as of January 1, 1986

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OF GENERAL APPLICABILITY
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AS OF JANUARY 1, 1986

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Cite this Code **CFR**

thus: **9 CFR 1.1**

READEX
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Explanation

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

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Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16	**as of January 1**
Title 17 through Title 27	**as of April 1**
Title 28 through Title 41	**as of July 1**
Title 42 through Title 50	**as of October 1**

The appropriate revision date is printed on the cover of each volume.

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The Paperwork Reduction Act of 1980 (Pub. L. 96-511) requires Federal agencies to display an OMB control number with their information collection request. Many agencies have begun publishing numerous OMB control numbers as amendments to existing regulations in the CFR. These OMB numbers are placed as close as possible to the applicable recordkeeping or reporting requirements.

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(b) The matter incorporated is in fact available to the extent necessary to afford fairness and uniformity in the administrative process.

(c) The incorporating document is drafted and submitted for publication in accordance with 1 CFR Part 51.

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III). A list of CFR Titles, Chapters, and Parts and an alphabetical list of agencies publishing in the CFR are also included in this volume.

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JOHN E. BYRNE,
Director,
Office of the Federal Register.

January 1, 1986

THIS TITLE

Title 9—ANIMALS AND ANIMAL PRODUCTS is composed of two volumes. The first volume contains Chapter I—Animal and Plant Health Inspection Service, Department of Agriculture (Parts 1-199) and the second volume contains Chapter II—Packers and Stockyards Administration, Department of Agriculture and Chapter III—Food Safety and Inspection Service, Meat and Poultry Inspection, Department of Agriculture (Part 200-End). The contents of these volumes represent all current regulations codified under this title of the CFR as of January 1, 1986.

For this volume Denise L. Landon was Chief Editor. The Code of Federal Regulations publication program is under the direction of Martha B. Girard, assisted by Robert E. Jordan.

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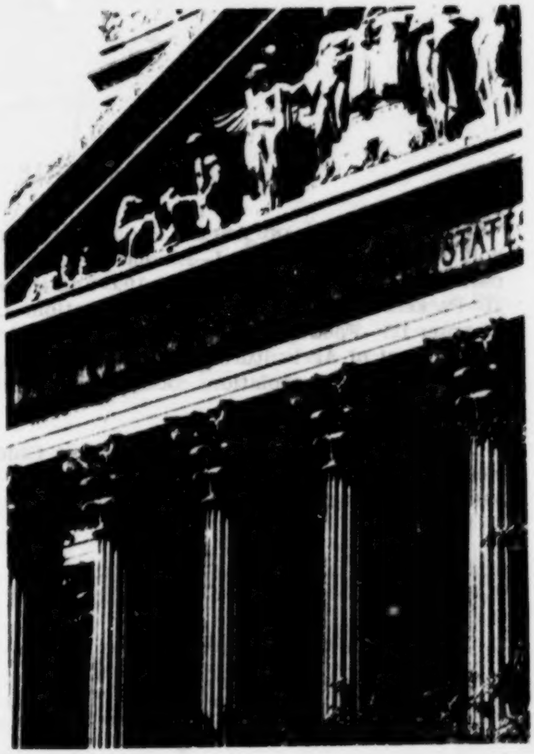

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Title 9—Animals and Animal Products

(This book contains Parts 1 to 199)

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NOTE: Other regulations issued by the Department of Agriculture appear in Title 7, Title 36, Chapter II, and Title 41, Chapter 4.

Title 9—Animals and Animal Products

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Editorial Note: Nomenclature changes affecting Subchapters A through J of this chapter appear at 37 FR 7493, Apr. 15, 1972.

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SUBCHAPTER A—ANIMAL WELFARE

PART 1—DEFINITION OF TERMS

§ 1.1 Definitions.

For the purposes of this part, unless the context otherwise requires, the following terms shall have the meanings assigned to them in this section. The singular form shall also import the plural and the masculine form shall also import the feminine. Words undefined in the following paragraphs shall have the meaning attributed to general usage as reflected by definition in a standard dictionary, such as "Webster's."

(a) "Act" means the Act of August 24, 1966 (Pub. L. 89-544), commonly known as the Laboratory Animal Welfare Act, as amended by the Act of December 24, 1970 (Pub. L 91-579), the Animal Welfare Act of 1970, and the Act of April 22, 1976 (Pub. L. 94-279), the Animal Welfare Act Amendments of 1976.

(b) "Department" means the U.S. Department of Agriculture.

(c) "Secretary" means the Secretary of Agriculture of the United States or his representative who shall be an employee of the Department.

(d) "Administrator" means Administrator of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or any other official of the Animal and Plant Health Inspection Service to whom authority has heretofore been delegated or to whom authority may hereafter be delegated, to act in his stead.

(e) "Veterinary Services" means the office of the Animal and Plant Health Inspection Service to which is assigned responsibility for the performance of functions under the Act.

(f) "Deputy Administrator" means the Deputy Administrator for Veterinary Services or any other official of Veterinary Services to whom authority has heretofore been delegated or to whom authority may hereafter be delegated, to act in his stead.

(g) "Veterinarian in Charge" means a veterinarian of Veterinary Service who is assigned by the Deputy Administrator to supervise and perform the official work of Veterinary Services in a given State or States. As used in Part 2 of this subchapter, the Veterinarian in Charge shall be deemed to be the one in charge of the official work of Veterinary Services in the State in which the dealer, exhibitor, research facility, intermediate handler, carrier, or operator of an auction sale has his principal place of business.[1]

(h) "Veterinary Services representative" means any inspector or other person employed by the Department who is responsible for the performance of the function involved.

(i) "Licensed veterinarian" means a doctor of veterinary medicine who has a valid license to practice veterinary medicine in any State.

(j) "State" means a State of the United States, the District of Columbia, Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, or any other territory or possession of the United States.

(k) "Persons" means any individual, partnership, firm, joint stock company, corporation, association, trust, estate, or other legal entity.

(l) "Dog" means any live or dead dog (*Canis familiaris*).

(m) "Cat" means any live or dead cat (*Felis catus*).

(n) "Animal" means any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or any other warmblooded animal, which is domesticated or raised in captivity or which normally can be found in the wild state, and is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet. Such term excludes birds, rats and mice, and horses and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock, or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs, including those used for hunting, security, or breeding purposes.

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[1] The name and address of the Veterinarian in Charge in the State concerned can be obtained by writing to the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, Hyattsville, MD 20782.

(o) "Farm animal" means any warm-blooded animal (other than a dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, or rabbit) normally raised on farms in the United States and used or intended for use as food or fiber.

(p) "Wild state" means living in its original, natural condition; not domesticated.

(q) "Nonhuman primate" means any nonhuman member of the highest order of mammals, including prosimians, monkeys, and apes.

(r) "Commerce" means trade, traffic, transportation, or other commerce—(1) between a place in a State and any place outside of such State, or between points within the same State but through any place outside thereof, or within any territory, possession, or the District of Columbia; or (2) which affects trade, traffic, transportation, or other commerce described in paragraph (r)(1) of this section.

(s) "Research facility" means any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that: (1) Purchases or transports live animals in commerce, or (2) receive funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States for the purpose of carrying out research, tests, or experiments: *Provided, however,* That a "research facility" shall not include any such school, institution, organization, or person that does not use or intend to use live dogs or cats and which is exempted by the Administrator, upon application to him in specific cases and upon his determination that such exemption does not vitiate the purpose of the Act, except that the Administrator will not exempt any school, institution, organization, or person that uses substantial numbers of live animals—the principal function of which school, institution, organization, or person is biomedical research or testing.[2]

(t) "Dealer" means any person who, in commerce, for compensation or profit, delivers for transportation, or transports, except as a carrier, buys, or sells, or negotiates the purchase or sale of, (1) any dog or other animal whether alive of dead for research, teaching, exhibition, or use as a pet, or (2) any dog for hunting, security, or breeding purposes, except that this term does not include: (i) A retail pet store except such store which sells any animals to a research facility, an exhibitor, or a dealer; or (ii) Any person who does not sell or negotiate the purchase or sale of any wild animal, dog, or cat, and who derives no more than $500 gross income from the sale of other animals during any calendar year.

(u) "Retail pet store" means any retail outlet where animals are sold only as pets at retail. Those species from the wild state (e.g., primates, anteaters, and ocelots) and which as adults in captivity require special conditions to provide safety in handling to either humans or the subject animals shall not be considered as pet animals.

(v) "Operator of an auction sale" means any person who is engaged in operating an auction at which animals are purchased or sold, in commerce.

(w) "Exhibitor" means any person (public or private) exhibiting any animals, which were purchased in commerce or the intended distribution of which affects commerce, or will affect commerce, to the public for compensation, as determined by the Secretary in specific instances, and such term includes carnivals, circuses, animal acts, and zoos exhibiting such animals whether operated for profit or not; but such term exludes retail pet stores, organizations sponsoring and all persons participating in State and county fairs, livestock shows, rodeos, purebred dog and cat shows, and any other fairs or exhibitions intended to advance agricultural arts and sciences, as may be determined by the Secretary in specific instances.

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[2] A list of such exempted schools, institutions, organizations, or persons shall be published periodically by Veterinary Services in the FEDERAL REGISTER. Such lists may also be obtained upon request from the Veterinarian in Charge.

(x) "Licensee" means any person licensed pursuant to the provisions of the Act and the regulations in Part 2 of this subchapter.

(y) "Class 'A' dealer" means a dealer whose business involving animals includes only those animals that he breeds and raises as a closed or stable colony and those animals that he acquires for the sole purpose of maintaining or enhancing his breeding colony.

(z) "Class 'B' dealer" means any dealer who does not meet the definition of a Class "A" dealer.

(aa) "Class 'C' licensee" means any exhibitor subject to the licensing requirements.

(bb) "Intermediate handler" means any person, including a department, agency, or instrumentality of the United States or of any State or local government (other than a dealer, research facility, exhibitor, or any person excluded from the definition of a dealer, research facility, exhibitor, an operator of an auction sale, or a carrier) who is engaged in any business in which he receives custody of animals in connection with their transportation in commerce.

(cc) "Carrier" means the operator of any airline, railroad, motor carrier, shipping line, or other enterprise which is engaged in the business of transporting any animals for hire.

(dd) "Registrant" means any research facility, carrier, intermediate handler, or exhibitor registered pursuant to the provisions of the Act and the regulations in Part 2 of this subchapter.

(ee) "Attending veterinarian" means a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates and who is responsible for evaluating the type and amount of anesthetic, analgesics, and tranquilizing drugs used on animals during actual research, testing, or experimentation where appropriate to relieve all unnecessary pain and distress in the subject animals.

(ff) "Standards" means the requirements with respect to the humane handling, care, treatment, and transportation of animals by dealers, exhibitors, research facilities, carriers, intermediate handlers, and operators of auction sales as set forth in Part 3 of this subchapter.

(gg) "Primary enclosure" means any structure used to immediately restrict an animal or animals to a limited amount of space, such as a room, pen, run, cage, compartment, pool, or hutch.

(hh) "Indoor housing facility" means any structure or building, housing or intended to house animals, which has the capability of controlling the environment within the enclosure created by the continuous connection of a roof, floor, and walls with at least one opening for entry and exit that is provided with a door or any movable structure used to close off the opening and typically consisting of a panel of wood, glass, metal, etc., which slides on rollers or swings on hinges: *Provided, however,* That any openings which provide natural light shall be covered with a transparent material, e.g., glass, plastic, etc.

(ii) "Outdoor housing facility" means any structure or building, housing or intended to house animals, which does not meet the definition of "indoor housing facility."

(jj) "Sanitize" means to make physically clean and to remove and destroy, to the maximum degree that is practical, agents injurious to health.

(kk) "Ambient temperature" means the temperature surrounding the animal.

(ll) "Euthanasia" means the humane destruction of an animal accomplished by a method which produces instantaneous unconsciousness and immediate death without visible evidence of pain or distress, or a method that utilizes anesthesia produced by an agent which cause painless loss of consciousness, and death following such loss of consciousness.

(mm) "Nonconditioned animals" means animals which have not been subjected to special care and treatment for sufficient time to stabilize and, where necessary, to improve their health to make them more suitable for research purposes.

(nn) "Weaned" means that an animal has become accustomed to take solid food, and has so done, without nursing, for a period of at least five (5) days.

(oo) "Dwarf hamster" means any species of hamster, such as the Chinese and Armenian species, whose adult body size is substantially less than that attained by the Syrian or Golden species of hamsters.

(pp) "Handling" means petting, feeding, manipulation, crating, shifting, transferring, immobilizing, restraining, treating, training, working or performing any similar activity with respect to any animal.

(qq) "Business year" means a 12-month period during which business is conducted, either on a calendar or fiscal year basis.

(rr) "Primary conveyance" means the main method of transportation used to convey an animal from origin to destination, such as a motor vehicle, plane, ship, or train.

(ss) "Transporting device" means an interim vehicle or device, other than man, used to transport an animal between the primary conveyance and the terminal facility or in and around the terminal facility of a carrier or intermediate handler.

(tt) "Minimum horizontal dimension" (MHD) means the diameter of a circular pool of water, or in the case of a square, rectangular, oblong or other shape pool, the diameter of the largest circle that can be inserted within the confines of such a pool of water

(Secs. 3, 5, 6, 10, 11, 12, 13, 14, 16, 17, 21; 80 Stat. 351, 352, 353, 84 Stat. 1561, 1562, 1563, 1564, 90 Stat. 418, 419, 420, 423 (7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2144, 2146,2147, 2151); 37 FR 28464, 28477, 38 FR 19141)

[42 FR 31022, June 17, 1977, as amended at 42 FR 31561, June 21, 1977; 44 FR 36874, June 22, 1979; 44 FR 63490, Nov. 2, 1979]

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AUTHORITY: Secs. 3, 5, 6, 10, 11, 12, 13, 14, 16, 17, 21; 80 Stat. 351, 352, 353; 84 Stat. 1561, 1562, 1563, 1564; 90 Stat. 418, 419, 420, 423; 7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2144, 2146, 2147, 2151, unless otherwise noted.

SOURCE: 36 FR 24920, Dec. 24, 1971, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 42 FR 31026, June 17, 1977.

LICENSING

§ 2.1 Application.

(a) Any person operating or desiring to operate as a dealer, exhibitor, or operator of an auction sale (where any dogs or cats are sold affecting commerce), except persons who are exempted from the licensing requirements under section 3 of the Act, shall apply for a license on a form which will be furnished, upon request, by the Veterinarian in Charge in the State in which such person operates or intends to operate. If such person operates in more than one State, he shall apply in the State in which he has his principal place of business. The completed application form shall be filed with such Veterinarian in Charge.

(b) Any person who is not a dealer or exhibitor, but who desires to obtain a license, shall follow the requirements for dealers and exhibitors set forth in paragraph (a) of this section and in §§ 2.2 and 2.3, and shall agree in writing, on a form furnished by Veterinary Services, to comply with all the requirements of the Act and the provisions of this subchapter. A license will be issued to any such applicant when the requirements of §§ 2.2 and 2.3 have been met, and when the applicant has submitted to the Veterinarian in Charge a fee of $5 by certified check, cashier's check, personal check, or money order. In addition to the fee required to be paid upon application for a license, such licensee shall submit to the Veterinarian in Charge a fee of $5, by certified check, cashier's check, personal check, or money order, on or before each anniversary date of his license. The failure of any such person to comply with any provisions of the Act, or any of the provisions of the regulations or standards in this subchapter, shall constitute grounds for automatic termination of such license or for its suspension or revocation by the Secretary.

(Approved by the Office of Management and Budget under the control number 0579-0036)

[36 FR 24920, Dec. 24, 1971, as amended at 44 FR 63491, Nov. 2, 1979; 48 FR 57471, Dec. 30, 1983]

§ 2.2 Acknowledgement of standards.

A copy of the applicable standards will be supplied to the applicant with each request for an application for a license, and the applicant shall acknowledge receipt of such standards and agree to comply with them by signing the application form provided for such purpose by Veterinary Services.

§ 2.3 Demonstration of compliance with standards.

Each applicant must demonstrate that his premises and any facilities or equipment used in his business comply with the standards set forth in Part 3 of this subchapter. Upon request by the Veterinarian in Charge, the applicant must make his premises, facilities, and equipment available at a time or times mutually agreeable to said applicant and Veterinary Services representative for the purpose of ascertaining compliance with said standards. If the applicant's premises, facilities, or equipment do not meet the requirements of the standards, the applicant will be advised of existing deficiencies and the corrective measures that must be taken and completed to bring such premises, facilities, and equipment into compliance with the standards.

[44 FR 63491, Nov. 2, 1979]

§ 2.4 Issuance of licenses.

Except as otherwise provided in §§ 2.10, and 2.11, a license will be issued to any applicant when the requirements of §§ 2.1, 2.2, and 2.3 have been met, when the Secretary has determined that the applicant's premises, facilities, and equipment comply with the standards and when the applicant has submitted to the Veterinarian in Charge the annual fee as prescribed in § 2.6 by certified check, cashier's check, personal check, or money order.

[44 FR 63491, Nov. 2, 1979]

§ 2.5 Duration of license.

(a) A license issued under this part shall be valid and effective unless:

(1) Said license has been revoked or suspended pursuant to section 19 of the Act.

(2) Said license is voluntarily terminated upon the request of the licensee in writing to the Veterinarian in Charge.

(b) Failure by a licensee to pay the annual license fee as required by §§ 2.1 and 2.6 or to file the annual report as required by § 2.7 on or before the anniversary date of his license shall result in automatic termination of the license: *Provided, however,* That prior to such termination the licensee shall be given notice and opportunity to comply with the annual license fee and reporting requirements. Failure to comply with the annual license fee and reporting requirements within 60 days from receipt of such notice shall result in automatic termination of license.

(c) A license which is invalid under paragraph (a) of this section shall be surrendered to the Veterinarian in Charge in the State where the license was issued.

[44 FR 63491, Nov. 2, 1979]

§ 2.6 Annual license fees.

(a) In addition to the fee required to be paid upon application for a license under § 2.4, each licensee shall submit to the Veterinarian in Charge the annual fee prescribed in this section, by certified check, cashier's check, personal check, or money order, on or before each anniversary date of his license.

(b)(1) Except as provided in paragraphs (b) (4) and (5) of this section, the annual fee for a Class "A" dealer shall be based on 50 percent of the total gross amount, expressed in dollars, derived from the sale of animals to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, directly or through an auction sale, by the dealer or applicant during his preceding business year (calendar or fiscal) in the case of a person who operated during such a year.

(2) Except as provided in paragraphs (b) (4) and (5) of this section, the annual fee for a Class "B" dealer shall be established by calculating the total amount received from the sale of animals to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, directly or through an auction sale, during his preceding business year (calendar or fiscal) less the amount paid for such animals, by the dealer or applicant. This net difference, exclusive of other costs, shall be the figure used to determine the license fee of such Class "B" dealer or applicant for a Class "B" license.

(3) Except as provided in paragraphs (b) (4) and (5) of this section, the amount of the annual license fee for an operator of an auction sale shall be that of a Class "B" dealer and shall be based on the total gross amount, expressed in dollars, derived from commissions or fees charged for the sale of animals at auction by the operator to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, during the preceding business year (calendar or fiscal).

(4) In the case of an applicant for a license as a dealer or operator of an auction sale who operated at least 6 months of his preceding business year but not the entire year, the annual license fee shall be computed by estimating the yearly volume of business on the basis of the business done during the period of operation.

(5) In the case of an applicant for a license as a dealer or operator of an auction sale who did not operate for at least six months during his preceding business year, the annual fee will be based on the anticipated yearly dollar amount of business, as provided in paragraphs (b) (1), (2), and (3) of this section, derived from the sale of animals to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, directly or through an auction sale.

(6) The amount of the annual fee required to be paid upon application for a license as an exhibitor under § 2.4, shall be based on the number of animals which are held by the applicant

at the time the application is signed and dated. The amount of the annual license fee for an exhibitor to be paid on or before each anniversary date of his license, shall be based on the number of animals which the exhibitor is holding at the time he signs and dates the annual report as required in § 2.7: *Provided, however,* That such report is not signed and dated more than 30 days prior to the anniversary date of the license.

(c) The license fee shall be computed in accordance with the following tables:

TABLE 1—DEALERS AND OPERATORS OF AN AUCTION SALE

Over	But not over	Fee
$0	$500	$5
500	2,000	15
2,000	10,000	25
10,000	25,000	100
25,000	50,000	200
50,000	100,000	300
100,000		500

TABLE 2—EXHIBITORS—CLASS "C" LICENSEE

Number of animals	*Fee*
1-5	$5
6-25	10
26-50	25
51-500	50
501 and up	100

(d) If a person meets the licensing requirements for more than one class of license, he shall be required to pay the fee for the type business which is predominant for his operation, as determined by the Secretary.

(e) In any situation in which a licensed dealer or operator of an auction sale shall have demonstrated in writing to the satisfaction of the Secretary that he has good reason to believe that his dollar amount of business, upon which the license fee is based, for the forthcoming business year will be less than the previous business year, then his estimated dollar amount of business shall be used for computing the license fee for the forthcoming business year: *Provided, however,* That if such dollar amount, upon which the license fee is based, for that year does in fact exceed the amount estimated, the difference in amount of the fee paid and that which was due based upon such actual dollar business upon which the license fee is based, shall be payable in addition to the required annual fee for the next subsequent year, on the anniversary date of his license as prescribed in this section.

[36 FR 24920, Dec. 24, 1971, as amended at 37 FR 26511, Dec. 13, 1972; 39 FR 28144, Aug. 5, 1974; 44 FR 63491, Nov. 2, 1979]

§ 2.7 Annual report by licensees.

(a) Each year within 30 days prior to the anniversary date of his license, a licensee shall file with the Veterinarian in Charge a report, upon a form which will be furnished to him, upon request, by the Veterinarian in Charge.

(b) A person licensed as a dealer shall set forth in his annual report the dollar amount of business, upon which the license fee is based, from the sale of animals, directly or through an auction sale, to research facilities for research, testing, experimentation, or teaching purposes; dealers; exhibitors; retail pet stores; and persons for use as pets, by the licensee during the preceding business year (calendar or fiscal) and such other information as may be required thereon.

(c) A person licensed as an operator of an auction sale shall set forth in his annual report the total gross amount, expressed in dollars, derived from commissions or fees charged for the sale of animals at auction by the licensee to research facilities, dealers, exhibitors, retail pet stores, and persons, for use as pets, during the preceding business year (calendar or fiscal), and such other information as may be required thereon.

(d) A person licensed as an exhibitor shall set forth in his annual report the number of animals which are held by him at the time he signs and dates the report: *Provided, however,* That such report is not signed and dated more than 30 days prior to the anniversary date of his license.

(Approved by the Office of Management and Budget under control number 0579-0036)

[36 FR 24920, Dec. 24, 1971, as amended at 37 FR 26511, Dec. 13, 1972; 44 FR 63492, Nov. 2, 1979; 48 FR 57471, Dec. 30, 1983]

§ 2.8 Notification of change of name, address, control or ownership of business.

A licensee shall promptly notify the Veterinarian in Charge of any change in the name, address, management or substantial control or ownership of his business or operation within 10 days after making such change.

§ 2.9 Officers, agents, and employees of licensees whose licenses have been suspended or revoked.

Any person who has been or is an officer, agent, or employee of a licensee whose license has been suspended or revoked and who was responsible for or participated in the violation upon which the order of suspension or revocation was based will not be licensed within the period during which the order of suspension or revocation is in effect.

§ 2.10 Licensees whose licenses have been suspended or revoked or terminated automatically.

Any person whose license has been suspended for any reason shall not again be licensed in his own name or in any other manner within the period during which the order of suspension is in effect, and any person whose license has been revoked shall not be eligible to apply for a new license in his own name or in any other manner for a period of 1 year from the effective date of such revocation. No partnership, firm, corporation, or other legal entity in which any such person has a substantial financial interest, will be licensed during such period. Any person who desires the reinstatement of a license which has automatically terminated must follow the procedure applicable to new licensees as explained in § 2.1.

[44 FR 63492, Nov. 2, 1979]

§ 2.11 Denial of license.

A license will be issued to any applicant when the requirements of §§ 2.1, 2.2, and 2.3 have been met; however, if the Secretary has reason to believe that the applicant is unfit to engage in the activity for which application has been made by reason of the fact that the applicant has within 2 years prior to filing the application engaged in any activity in violation of any provisions of the Act, the regulations, or standards, which previously has not been the subject of an administrative proceeding under the Act resulting in the imposition of a sanction against the applicant, an administrative proceeding shall be promptly instituted in which the applicant will be afforded an opportunity for a hearing in accordance with the rules of practice under the Act, for the purpose of the applicant showing cause why the application for license should not be denied. In the event it is determined that the application should be denied, the applicant shall not be precluded from again applying for a license after one year from the date of the final order denying the application.

[39 FR 28144, Aug. 5, 1974]

REGISTRATION

§ 2.25 Requirements and procedures.

Each research facility, carrier, and intermediate handler and each exhibitor, not required to be licensed under section 3 of the Act and the regulations of this subchapter, shall register with the Secretary by completing and filing a properly executed form which will be furnished, upon request, by the Veterinarian in Charge. Such registration form shall be file with the Veterinarian in Charge for the State in which the registrant has his principal place of business. Where a school or department of a university or college uses or intends to use animals for research, tests, or experiments, the university or college rather than the school or department will generally be considered the research facility and be required to register with the Secretary. In any situation in which a school or department of a university or college is a separate legal entity and its operations and administration are independent of those of the university or college, upon a proper showing thereof to the Secretary, the school or department will be registered rather than the university or college. A subsidiary of a business corporation, rather than a parent corporation, will be registered as a research facility or exhibitor unless the subsidiary is under such direct control of the parent corporation that to effectuate the purposes of the Act, the Secretary determines that it is necessary that the parent corporation be registered.

(Approved by the Office of Management and Budget under control number 0579-0036)

[42 FR 31026, June 17, 1977, as amended at 48 FR 57471, Dec. 30, 1983]

§ 2.26 Acknowledgment of standards.

A copy of the applicable standards will be supplied with each registration form, and the registrant shall acknowledge receipt of such standards and agree to comply with them by signing a form provided for such purpose by Veterinary Services. Such form shall be filed with the Veterinarian in Charge.

(Approved by the Office of Management and Budget under control number 0579-0036)

[36 FR 24920, Dec. 24, 1971, as amended at 48 FR FR 57471, Dec. 30, 1983]

§ 2.27 Notification of change of operation.

A registrant shall promptly notify the Veterinarian in Charge of any change in his name or address or any change in his operations which would affect his status as a research facility or exhibitor within ten days after making such change.

§ 2.28 Annual report of research facilities.

(a) The reporting facility shall be that segment of the research facility, or that department, agency, or instrumentality of the United States, that uses or intends to use live animals in research, tests, or experiments and for which an attending veterinarian has responsibility. Each reporting facility shall submit on or before December 1 of each calendar year to the Veterinarian in Charge for the State where the reporting facility is located, an annual report signed by a legally responsible official covering the previous Federal fiscal year of October 1 through September 30. Such report shall show that professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, during actual research, testing, or experimentation, were followed by the research facility, department, agency, or instrumentality of the United States. Such report shall include:

(1) The location of the facility or facilities where animals were used in actual research, testing, or experimentation;

(2) The common names and approximate numbers of animals upon which research, experiments, or tests were conducted involving no pain, distress, or use of pain relieving drugs: *Provided, however,* That routine procedures (e.g., injections, tattooing, and blood sampling) do not need to be reported;

(3) The common names and approximate numbers of animals upon which experiments or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used: *Provided, however,* That routine procedures (e.g., injections, tattooing, and blood sampling) do not need to be reported;

(4) The common names and approximate numbers of animals upon which experiments or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would adversely affect the procedures, results, or interpretation of the research, experiments, or tests and a brief statement explaining the reasons for the same: *Provided, however,* That routine procedures (e.g., injections, tattooing, and blood sampling) do not need to be reported; and

(5) Certification by the attending veterinarian of the research facility, or the department, agency, or instrumentality of the United States having laboratory animal facilities, or by an institutional committee of at least three members, one of whom is a Doctor of Veterinary Medicine, established for the purpose of evaluating the care, treatment, and use of all warmblooded animals held or used for research, testing, or experimentation, that the type and amount of anesthetic, analgesic, and tranquilizing drugs

used on animals during actual research, testing, or experimentation was appropriate to relieve pain and distress for the subject animals.

(Approved by the Office of Management and Budget under control number 0579-0036)

[42 FR 31026, June 17, 1977, as amended at 48 FR FR 57471, Dec. 30, 1983]

IDENTIFICATION OF ANIMALS

§ 2.50 Time and method of identification.

(a) Except as otherwise provided in this section, when a Class A dealer sells or otherwise removes dogs or cats from his premises for delivery, affecting commerce, to a research facility or exhibitor or to another dealer, or for sale, affecting commerce, through an auction sale or to any person for use as a pet, each such dog or cat shall be identified by an official tag of the type described in § 2.51 affixed to the animal's neck by means of a collar made of material generally considered acceptable to pet owners as a means of identifying their pet dogs or cats:[1] *Provided, however,* That no official tag need be affixed to any such dog that has been identified by means of a distinctive and legible tattoo marking acceptable to the Deputy Administrator: *And provided further,* That no official tag need be affixed to any puppy or kitten less than 16 weeks of age that is identified by means of a plastic type collar acceptable to the Deputy Administrator and which has the information (which shall be legibly placed thereon) as required for an official tag pursuant to § 2.51.

(b) Except as otherwise provided in this section, when a Class B dealer or exhibitor purchases or otherwise acquires a dog or cat, affecting commerce, he shall immediately affix to such animal's neck an official tag of the type described in § 2.51 by means of a collar made of material generally acceptable to pet owners as a means of identifying their pet dogs or cats, but if the dog or cat is not purchased or acquired, affecting commerce, by said dealer or exhibitor, such animal must be so tagged at the time it is delivered for transportation, transported, or sold, affecting commerce, by said dealer or exhibitor:[1] *Provided, however,* That if such dog or cat is already identified by an official tag which has been applied by another dealer or exhibitor, it is not necessary that any subsequent dealer or exhibitor replace the tag on such animal, but the Class B dealer or exhibitor may replace such previously attached tag with his own official tag, and in which event, the Class B dealer or exhibitor shall correctly list both official tag numbers in his records of purchase which shall be maintained in accordance with §§ 2.75 and 2.77 and the new official tag number shall be used on all records of subsequent sales of such dog or cat: *And provided further,* That no official tag need be affixed to any such dog or cat that has been identified by means of a distinctive and permanent tattoo marking approved by the Deputy Administrator: *And provided still further,* That no official tag need be affixed to any puppy or kitten less than 16 weeks of age that has been identified by means of a plastic type collar acceptable to the Deputy Administrator and which has the information (which shall be legibly placed thereon) as required for an official tag pursuant to § 2.51.

(c) When any dealer or exhibitor has made a reasonable effort to affix an official tag to an adult cat, as set forth in paragraphs (a) and (b) of this section, and has been unable to do so, or when the cat exhibits extreme distress from the attachment of a collar and tag, the dealer or exhibitor shall attach the collar and tag, to the door of the primary enclosure containing the cat and take proper measures to maintain the identity of the cat in relation to the tag. Each primary enclosure shall contain no more than one adult cat without an affixed collar and official tag.

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[1] In general, well fitted collars made of leather or plastic will be acceptable under this provision. The use of certain types of chains presently used by some dealers may also be deemed acceptable. A determination of the acceptability of a material proposed for usage as collars from the standpoint of humane considerations will be made by Veterinary Services on an individual basis in consultation with the dealer or exhibitor involved. The use of materials such as wire or elastic that might readily cause discomfort or injury to dogs or cats will not be acceptable.

(d) Unweaned puppies or kittens need not be individually identified as required by paragraphs (a) and (b) of this section while they are maintained as a litter with their dam in the same primary enclosure provided she has been so identified.

(e) All live dogs or cats delivered for transportation, transported, purchased, or sold, affecting commerce, by a research facility, shall be identified, at the time of such delivery for transportation, purchase, or sale, by the official tag or tattoo, which was affixed to the animal at the time it was acquired by the research facility, as provided in paragraph (a) of this section, or by a tag, tattoo, or collar, applied to the live dog or cat by the research facility and which individually identifies such dog or cat by description or number.

(f)(1) All animals, except dogs and cats, delivered for transportation, transported, purchased, or sold, affecting commerce, by any dealer or exhibitor shall be identified by the dealer or exhibitor at the time of such delivery for transportation, transportation, purchase, or sale, as provided in this paragraph.

(2) When one or more animals, other than dogs or cats, are confined in a container, the animal or animals shall be identified by (i) a label attached to the container which shall bear a description of the animals in the container, including the number of animals, species of the animals, any distinctive physical features of the animals, and any identifying marks, tattoos, or tags attached to the animals, (ii) marking the container with a painted or stenciled number, which number shall be recorded in the records of the dealer or exhibitor together with a description of the animal or animals, including the species, and any distinctive physical features of the animal; or (iii) by a tag or tattoo applied to each animal in the container by the dealer or exhibitor and which individually identifies such animal by description or number.

(3) When any animal, other than a dog or cat, is not confined in a container, it shall be identified on a record, as required by § 2.75 which shall accompany the animal at the time it is delivered for transportation, transported, purchased, or sold, affecting commerce, and shall be kept and maintained by the dealer or exhibitor as part of his records.

[36 FR 24920, Dec. 24, 1971, as amended at 42 FR 31026, June 17, 1977]

§ 2.51 Form of official tag.

The official tag shall be made of a durable alloy such as brass, bronze, or steel or of a durable plastic. Aluminum of a durable thickness and quality may be used. Such tag shall be circular in shape and not less than 1¼ inches in diameter. Each tag shall be embossed or stamped with the letters "USDA" and numbers and letters identifying the State, dealer, and animal, as set forth in Figure 1. Such tags shall be serially numbered and there shall be no duplication of numbers by any one dealer or exhibitor.

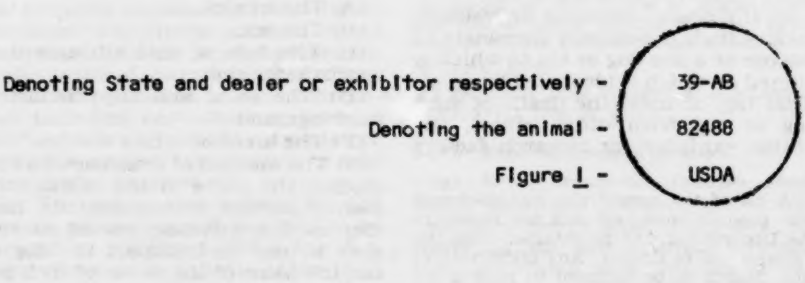

Figure 1 -

§ 2.52 How to obtain tags.

Dealers or exhibitors may obtain, at their own expense, official tags from commercial tag manufacturers.[2] At the time a dealer or exhibitor is issued a license, the Department will assign him dealer or exhibitor identification letters and inform him of the State number to be used on his official tags.

§ 2.53 Use of tags.

Official tags obtained by a dealer or exhibitor shall be applied to dogs or cats in the manner set forth in § 2.50 and in as near consecutive numerical order as possible. No tag number shall be used to identify more than one animal.

§ 2.54 Lost tags.

Each dealer or exhibitor shall be held accountable for all official tags that he acquires. In the event an official tag is lost from the neck of a dog or cat while in the possession of a dealer or exhibitor, a diligent effort shall be made to locate and reapply such tag to the proper animal. If the lost tag is not located, the dealer or exhibitor shall affix another official tag to the animal in the manner prescribed in § 2.50, and make a notation of the tag number on his official records.

§ 2.55 Removal of tag.

(a) When a dog or cat wearing or identified by an official tag arrives at a research facility, such tag shall be removed and retained by the research facility: *Provided, however,* That at the discretion of the research facility such tag may be used to continue the identification of such dog or cat.

(b) If a dealer, exhibitor or research facility finds it necessary humanely to dispose of a live dog or cat to which is affixed or which is identified by an official tag, or upon the death of such dog or cat from other causes, the dealer, exhibitor, or research facility shall remove and retain such tag for the required period.

(c) All official tags removed and retained by a dealer, exhibitor, or research facility shall be held until called for by a Veterinary Services representative or for a period of 1 year.

(d) When official tags are disposed of, they must be disposed of in such a manner as to preclude their reuse as animal identification.

RECORDS

§ 2.75 Records, dealers and exhibitors.

(a)(1) Every dealer and exhibitor shall make, keep, and maintain systems of records or forms which fully and correctly disclose the following information concerning each dog or cat purchased or otherwise acquired, owned, held, or otherwise in his possession or under his control, including any offspring born of such animal while in his possession or under his control, transported, or sold, or otherwise disposed of:

(i) The name and address of the person, whether or not required to be licensed or registered under the Act, from whom such dog or cat was purchased or otherwise acquired, and his license number, if licensed under the Act, and when sold or otherwise disposed of, the person to whom sold or otherwise disposed of, and his license number, if licensed under the Act;

(ii) The dates of acquistion and disposition of such dog or cat;

(iii) The official USDA tag number or tattoo assigned to such dog or cat pursuant to §§ 2.50 and 2.54;

(iv) A description of each dog or cat which shall include:

(A) The species;

(B) The sex;

(C) The date of birth (if known) or approximate age;

(D) The color and any distinctive markings; and

(E) The breed or type.

(v) The method of transportation including the name of the initial commercial carrier or intermediate handler or if a privately owned conveyance is used to transport the dog or cat, the name of the owner of such privately owned conveyance.

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[2] A list of the commercial manufacturers who produce such tags and are known to the Department may be obtained from the Veterinarian in Charge. Any manufacturer who desires to be included in such a list should notify the Deputy Administrator.

(vi) The date and method of disposition of such dog or cat, e.g., sale, death, euthanasia, or donation.

(2) Record of Dogs and Cats on Hand (VS Form 18-5) and Record of Disposition of Dogs and Cats (VS Form 18-6) are forms which may be used by dealers and exhibitors upon which to make, keep, and maintain the information required by paragraph (a)(1) of this section concerning dogs and cats except as provided in § 2.79.

(3) The USDA Individual Health Certificate and Identification Form (VS Form 18-1) and the USDA Multianimal Health Certificate and Identification Form (VS Form 18-2) are forms which may be used by dealers and exhibitors upon which to make, keep, and maintain the information required by paragraph (a)(1) of this section and § 2.79.

(4) One copy of the record containing the information required by paragraph (a)(1) of this section shall accompany each shipment of any dog or cat purchased or otherwise acquired by a dealer or exhibitor. One copy of the record containing the information required by paragraph (a)(1) of this section shall accompany each shipment of any dog or cat sold or otherwise disposed of by a dealer or exhibitor: *Provided, however,* That information which indicates the source and date of acquisition of such dog or cat is not required to appear on the copy of the record accompanying the shipment. One copy of the record containing the information required by paragraph (a)(1) of this section shall be retained by the dealer or exhibitor.

(b)(1) Every dealer and exhibitor shall make, keep, and maintain systems or records or forms which fully and correctly disclose the following information concerning animals other than dogs and cats, purchased or otherwise acquired, owned, held, or otherwise in his possession or under his control, including any offspring born of such animals while in his possession or under his control, transported, or sold or otherwise disposed of:

(i) The name and address of the person, whether or not required to be licensed or registered under the Act, from whom such animals other than dogs or cats, were purchased or otherwise acquired, and his license number, if licensed under the Act, and when sold or otherwise disposed of, the person to whom sold or otherwise disposed of, and his license number, if licensed under the Act;

(ii) The species of such animals other than dogs and cats; and

(iii) The number of such animals other than dogs and cats.

(2) Record of Animals on Hand (Other Than Dogs and Cats) (VS Form 18-19) and Record of Acquisition, Disposition, or Transport of Animals (Other Than Dogs and Cats) (VS Form 18-20) are forms which may be used by dealers, and exhibitors upon which to keep and maintain the information required by paragraph (b)(1) hereof concerning animals other than dogs and cats except as provided in § 2.79.

(3) One copy of the record containing the information required by paragraph (b)(1) of this section shall accompany each shipment of any animal other than a dog or cat purchased or otherwise acquired by a dealer or exhibitor. One copy of the record containing the information required by paragraph (b)(1) of this section shall accompany each shipment of any animal other than a dog or cat sold or otherwise disposed of by a dealer or exhibitor: *Provided, however,* That information which indicates the source and date of acquisition of any animal other than a dog or cat is not required to appear on the copy of the record accompanying the shipment. One copy of the record containing the information required by paragraph (b)(1) of this section shall be retained by the dealer or exhibitor.

(Approved by the Office of Management and Budget under control numbers 0579-0028, 0579-0037, 0579-0038 and 0579-0068)

(44 U.S.C. 3506)

[42 FR 31026, June 17, 1977, as amended at 48 FR 57471, Dec. 30, 1983]

§ 2.76 Records, research facilities.

(a) Every research facility shall make, keep, and maintain systems of records or forms which fully and correctly disclose the following information concerning each live dog or cat purchased or otherwise acquired, owned, held, or otherwise in its possession or under its control, including any offspring born of such live dog or cat while in its possession or under its control:

(1) The name and address of the person, whether or not required to be licensed or registered under the Act, from whom such live dog or cat was purchased or otherwise acquired and his license number, if licensed under the Act;

(2) The date of acquisition of each live dog or cat;

(3) The official USDA tag number or tattoo assigned to each live dog or cat pursuant to §§ 2.50 and 2.54;

(4) A description of each live dog or cat which shall include:

(i) The species;

(ii) The sex;

(iii) Date of birth (if known) or approximate age;

(iv) The color and any distinctive markings; and

(v) The breed or type.

(5) Any identification number or mark assigned to each live dog or cat by such reserach facility.

(b) In addition to the information required to be kept and maintained by every research facility concerning each live dog or cat, pursuant to paragraph (a) of this section, every research facility transporting, selling, or otherwise disposing of any live dog or cat to another person, shall make, keep, and maintain systems of records or forms which fully and correctly disclose the following information:

(1) The name and address of the receiver to whom such live dog or cat is transported, sold or otherwise disposed of;

(2) The date of such transportation, sale or other disposition, and

(3) The method of transportation including the name of the initial commercial carrier or intermediate handler or if a privately owned conveyance is used to transport the dog or cat, the name of the owner of such privately owned conveyance.

(c) The USDA Individual Health Certificate and Identification Form (VS Form 18-1), The USDA Multianimal Health Certificate and Identification Form (VS 18-2), and Record of Dogs and Cats on Hand (VS Form 18-5) are forms which may be used by research facilities upon which to keep and maintain the information required by paragraph (a) of this section. The USDA Individual Health Certificate and Identification Form (VS Form 1), the USDA Multianimal Health Certificate and Identification Form (VS Form 18-2), and Record of Disposition of Dogs and Cats and (VS Form 18-6) are forms which may be used by research facilities upon which to keep and maintain the information required by paragraph (b) of this section.

(d) One copy of the record containing the information required by paragraphs (a) and (b) of this section shall accompany each shipment of any live dog or cat sold, or otherwise disposed of by a research facility: *Provided, however,* That information which indicates the source and date of acquisition of any dog or cat is not required to appear on the copy of the record accompanying the shipment. One copy of the record containing the information required by paragraphs (a) and (b) of this section shall be retained by the research facility.

(Approved by the Office of Management and Budget under control numbers 0579-0028, 0579-0037, 0579-0038 and 0579-0068)

(44 U.S.C. 3506)

[42 FR 31026, June 17, 1977, as amended at 48 FR 57471, Dec. 30, 1983]

§ 2.77 Records, operators of auction sales.

(a) Every operator of an auction sale shall make, keep, and maintain systems of records or forms which fully and correctly disclose the following information concerning each animal consigned for auction, whether or not a fee or commission is charged:

(1) The name and address of the person who owned or consigned the animal for sale and his USDA license number, if licensed under the Act;

(2) The date of the consignment;

(3) The official USDA tag number or tattoo assigned to the animal pursuant to §§ 2.50 and 2.54;

(4) A description of the animal which shall include:

(i) The species of the animal;

(ii) The sex of the animal;

(iii) The color and any distinctive markings on the animal;

(iv) The breed or type of the animals, if a dog or cat.

(5) The auction sales number assigned to the animal;

(6) The name and address of the buyer of the animal and his license number, if licensed under the Act.

(b) One copy of the record containing the information required by paragraph (a) of this section shall be given to the consignor of each animal, one copy of the record shall be given to the purchaser of each animal: *Provided, however,* That information which indicates the source and date of consignment of any animal is not required to appear on the copy of the record given to the purchaser of any animal. One copy of the record containing the information required by paragraph (a) of this section shall be retained by the operator of such auction sale for each animal sold by the auction sale.

(Approved by the Office of Management and Budget under control numbers 0579-0028, 0579-0037, 0579-0038 and 0579-0068)

(44 U.S.C. 3506)

[42 FR 31026, June 17, 1977, as amended at 48 FR 57471, Dec. 30, 1983]

§ 2.78 Records, carriers and intermediate handlers.

(a) In connection with all live animals accepted for shipment on a C.O.D. basis or other arrangement or practice under which the cost of such animal or the cost of the transportation of such animal is to be paid and collected upon delivery of the animal to the consignee, the accepting carrier or intermediate handler, if any, shall keep and maintain a copy of the guarantee in writing of the consignor of such shipment for the payment of transportation charged for any animal not claimed as provided in § 2.80, including, where necessary, both the return transportation charges and an amount sufficient to reimburse the carrier for out-of-pocket expenses incurred for the care, feeding, and storage of such animal. The carrier or intermediate handler at destination shall also keep and maintain a copy of the shipping document containing the time, date, and method of each attempted notification and the final notification to the consignee and the name of the person notifying the consignee, as provided in § 2.80.

(b) In connection with all live dogs, cats, or nonhuman primates delivered for transportation, in commerce, to any carrier or intermediate handler, by any dealer, research facility, exhibitor, operator of an auction sale, or department, agency, or instrumentality of the United States or of any State or local government, the accepting carrier or intermediate handler shall keep and maintain a copy of the health certification completed as required by § 2.79, tendered with each such live dog, cat, or nonhuman primate.

(Approved by the Office of Management and Budget under control numbers 0579-0028, 0579-0037, 0579-0038, and 0579-0068)

(44 U.S.C. 3506)

[42 FR 31026, June 17, 1977, as amended at 48 FR 57471, Dec. 30, 1983]

§ 2.79 Health certification and identification.

(a) No dealer, research facility, exhibitor, operator of an auction sale, or department, agency, or instrumentality of the United States or of any State or local government shall deliver to any intermediate handler or carrier for transportation, in commerce, any dog, cat, or nonhuman primate unless such dog, cat, or nonhuman primate shall be accompanied by a health certificate executed and issued by a licensed veterinarian such health certificate shall state that (1) the licensed veterinarian inspected such dog, cat, or nonhuman primate on a specified date which shall not be more than 10 days prior to the delivery of such dog, cat, or nonhuman primate for transportation, in commerce, and (2) when so inspected that such dog, cat, or nonhuman primate appeared to the licensed veterinarian to be free of any infectious disease or physical abnormality which would endanger the animal or animals or other animals or endanger public health.

(b) No intermediate handler or carrier to whom any live dog, cat, or nonhuman primate is delivered for transportation, in commerce, by any dealer, research facility, exhibitor, operator of an auction sale, or department, agency, or instrumentality of the

United States or any State or local government shall receive such live dog, cat, or nonhuman primate for transportation, in commerce, unless and until it is accompained by a health certificate issued by a licensed veterinarian pursuant to paragraph (a) of this section.

(c) The USDA Individual Health Certificate and Identification Form (VS Form 18-1) and the USDA Multianimal Health Certificate and Identification Form (VS Form 18-2) are forms which may be used for health certification by a licensed veterinarian as required by this section.

(Approved by the Office of Management and Budget under control numbers 0579-0028, 0579-0037, 0579-0038, and 0579-0068)

(44 U.S.C. 3506)

[42 FR 31026, June 17, 1977, as amended at 48 FR 57471, Dec. 30, 1983]

§ 2.80 C.O.D. shipments.

(a) No carrier or intermediate handler shall accept any animal for transportation, in commerce, upon any C.O.D. or other basis where the cost of the animal or the cost for any such transportation or any other incidental or out-of-pocket expense is to be paid and collected upon delivery of such animal to the consignee, unless the consignor guarantees in writing the payment of all transportation, including any return transportation, if such shipment is unclaimed or the consignee cannot be notified in accordance with paragraphs (b) and (c) of this section, including reimbursing the carrier or intermediate handler for all out-of-pocket expenses incurred for the care, feeding, and storage or housing of such animal.

(b) Any carrier or intermediate handler receiving any animal at destination on a C.O.D. or other basis where the cost of the animal or the cost for any transportation or other incidental or out-of-pocket expense is to be paid and collected upon delivery of such animal to the consignee shall attempt to notify such consignee for period of 24 hours after arrival of the animal at the animal holding area of the terminal cargo facility, at least once every 6 hours during that period. The time, date, and method of each attempted notification and the final notification to the consignee and the name of the person notifying the consignee shall be recorded by the carrier or intermediate handler on the shipping document and a copy thereof, accompanying the C.O.D. shipment. If the consignee cannot be notified of the C.O.D. shipment within 24 hours after arrival of the shipment, the carrier or intermediate handler shall return the animal to the consignor, or to whomever the consigner has designated, on the next practical available transportation, in accordance with the written agreement required in paragraph (a) of this section and so notify the consignor.

Any carrier or intermediate handler which has notified a consignee of the arrival of a C.O.D. or other shipment of an animal, where the cost of the animal, or the cost for any transportation, or other incidental or out-of-pocket expense is to be paid and collected upon delivery of such animal to the consignee, which is not claimed by such consignee within 48 hours from the time of such notification, shall return the animal to the consignor, or to whomever the consignor has designated, on the next practical available transportation, in accordance with the written agreement required in paragraph (a) of this section and so notify the consignor.

(c) It shall be the responsibility of any carrier or intermediate handler to provide proper care, feeding, and storage or housing for any animal accepted for transportation, in commerce, under a C.O.D. or other arrangement where the cost of the animal or the cost of any transportation or other incidental or out-of-pocket expense is to be paid and collected upon delivery of such animal until the consignee accepts shipment at destination or until returned to the consignor or his designee should the consignee fail to accept delivery of the animal or the consignee could not be notified as prescribed in paragraph (b) of this section.

(d) Nothing in this section shall be construed as prohibiting any carrier or intermediate handler from requiring any additional guarantee than that required in paragraph (a) of this section for the payment of the cost of any transportation or out-of-pocket or other incidental expenses incurred in the transportation of any animal in commerce.

(Approved by the Office of Management and Budget under control numbers 0579-0028, 0579-0037, 0579-0038, and 0579-0068)

(44 U.S.C. 3506)

[42 FR 31026, June 17, 1977, as amended at 48 FR 57471, Dec. 30, 1983]

§ 2.81 Records, disposition.

(a) No dealer, exhibitor, operator of an auction sale, research facility, carrier, or intermediate handler shall, within a period of one year from the making thereof, destroy or dispose of, without the consent in writing of the Deputy Administrator, any books, records, documents, or other papers required to be kept and maintained under this part.

(b) The records required to be kept and maintained under this part shall be held for such period in excess of this period specified in paragraph (a) of this section as necessary to comply with any other Federal, State, or local law. Whenever the Deputy Administrator notifies a dealer, exhibitor, operator of an auction sale, reserach facility, carrier, or intermediate handler in writing that specified records shall be retained pending completion of an investigation or proceeding under the Act, such dealer, exhibitor, operator of an auction sale, research facility, carrier, or intermediate handler shall hold such records until their disposition is authorized by the Deputy Administrator.

(Approved by the Office of Management and Budget under control numbers 0579-0028, 0579-0037, 0579-0038, and 0579-0068)

(44 U.S.C. 3506)

[42 FR 31026, June 17, 1977, as amended at 48 FR 57471, Dec. 30, 1983]

COMPLIANCE WITH STANDARDS AND HOLDING PERIOD

§ 2.100 Compliance with standards.

(a) Each dealer, exhibitor, operator of an auction sale, and research facility shall comply in all respects with the standards set forth in Part 3 of this subchapter setting forth the standards for the humane handling, care, treatment, and transportation of animals: *Provided, however,* That nothing in these rules, regulations, or standards shall effect or interfere with the design, outlines, guidelines, or performances of actual research or experimentation by a research facility as determined by such research facility.

(b) Each carrier and intermediate handler shall comply in all respects with the standards set forth in Part 3 of the subchapter setting the standards for the humane transportation of animals in commerce, and their handling, care, and treatment in connection therewith.

[36 FR 24920, Dec. 24, 1971, as amended at 42 FR 31561, June 21, 1977]

§ 2.101 Holding period.

(a) Any dog or cat acquired by a dealer[4] or exhibitor shall be held by him, under his supervision and control, for a period of not less than 5 business days after acquisition of such animal: *Provided, however,* That (1) dogs or cats which have completed a 5-day holding period may be disposed of by subsequent dealers or exhibitors after a minimum holding period of 1 calendar day by each such subsequent dealer or exhibitor, excluding time in transit; (2) any dog or cat suffering from disease, emaciation or injury may be destroyed by euthanasia prior to the completion of the holding period required by this section. (For purposes of this paragraph, "business day" shall mean any day of the week during which the dealer or exhibitor normally operates his business. For purposes of this paragraph, "calendar day" shall mean from midnight of the day when an animal is received until the next midnight (example: If a dog or cat is received at 6 p.m. on the third day of a month, the "calendar day" referenced in the proviso would not expire until the morning of the fifth day.))

(b) During the period in which any dog or cat is being held as required by this section, such dog or cat shall be unloaded from any means of conveyance in which it was received, for feed, water, and rest, and handled, cared for, and treated in accordance with the standards set forth in §§ 3.1 through 3.10 of this subchapter.

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[4] An operator of an auction sale is not considered to have acquired a dog or cat which is sold through the auction sale.

(c) If any dealer or exhibitor obtains the prior approval of the Veterinarian in Charge, he may arrange to have another person hold such animals for the required period provided for in paragraph (a) of this section: *Provided, however,* That such other person agrees in writing to comply with the regulations of this Part 2 and the standards in Part 3 of this subchapter and to allow inspection by a Veterinary Services representative of his premises: *And provided further,* That the dogs and cats still remain under the control of the dealer or exhibitor: *And provided further,* That approval will not be given for a dealer or exhibitor holding a license as set forth in § 2.4 to have animals held for purposes of this section by another licensed dealer or exhibitor.

MISCELLANEOUS

§ 2.125 Information as to business; furnishing of by dealers, exhibitors, operators of auction sales, and research facilities.

Each dealer, exhibitor, operator of an auction sale, and research facility shall furnish to any Veterinary Services representative, any information concerning the business of the dealer, exhibitor, operator of an auction sale, or research facility which may be requested by such representative in connection with the enforcement of the provisions of the Act, the regulations and the standards in this subchapter. Such information shall be furnished within such reasonable time as may be specified in the request for such information.

§ 2.126 Access and inspection of records and property.

Each dealer, exhibitor, operator of an auction sale, or research facility, shall, during ordinary business hours, permit Veterinary Services representatives, or other Federal officers or employees designated by the Secretary, to enter his place of business to examine records required to be kept by the Act and the regulations in this part, and to make copies of such records, and permit Veterinary Services representatives to enter his place of business, to inspect such facilities, property and animals as such representatives consider necessary to enforce the provisions of the Act, the regulations and the standards in this subchapter. The use of a room, table, or other facilities necessary for the proper examination of such records and inspection of such property or animals shall be extended to such authorized representatives of the Secretary by the dealer, exhibitor, operator of an auction sale, or research facility, his agents and employees.

(Approved by the Office of Management and Budget under control numbers 0579-0028, 0579-0037, 0579-0038, and 0579-0068)

[36 FR 24920, Dec. 24, 1971, as amended at 48 FR FR 57471, Dec. 30, 1983]

§ 2.127 Publication of names of persons subject to the provisions of this part.

Lists of persons licensed or registered, pursuant to the provisions of this part, shall be published periodically by Veterinary Services in the FEDERAL REGISTER. Such lists may also be obtained, upon request, from the Veterinarian in Charge.

§ 2.128 Inspection for missing animals.

(a) Each dealer, exhibitor, operator of an auction sale and research facility shall, upon request, during ordinary business hours, permit, under the following conditions, police or law officers of legally constituted law enforcement agencies with general law enforcement authority (not those agencies whose duties are limited to enforcement of local animal regulations) to enter the place of business of such dealer, exhibitor, operator of an auction sale or research facility to inspect animals and records for the purpose of seeking animals that are missing:

(1) The police or law officer shall furnish to the dealer, exhibitor, operator of an auction sale or research facility a written description of the missing animal and the name and address of its owner before making such a search.

(2) The police or law officer shall abide by all security measures required by the dealer, exhibitor, operator of an auction sale or research facil-

ity to prevent the spread of disease, including the use of sterile clothing, footwear, and masks where required, or to prevent the escape of an animal.

(b) Such inspection for missing animals by law enforcement officers shall not extend to animals that are undergoing actual research or experimentation by a research facility as determined by such research facility.

§ 2.129 Confiscation and destruction of animals.

(a) If an animal being held by a dealer, exhibitor, or operator of an auction sale, or an animal being held by a research facility which is no longer required by such research facility to carry out the research, test, or experiment for which it has been utilized, is found by a Veterinary Services representative to be suffering as a result of the failure of the dealer, exhibitor, operator of an auction sale, or research facility to comply with any provision of the regulations or the standards set forth in this subchapter, the Veterinary Services representative shall make a reasonable effort to notify the dealer, exhibitor, operator of an auction sale, or research facility of the condition of such animal and request that the condition be corrected and that adequate veterinary care be given when necessary to alleviate the animal's suffering, or that the animal be destroyed by euthanasia. In the event that the dealer, exhibitor, operator of an auction sale or research facility refuses to comply with such request, the Veterinary Services representative may confiscate or destroy such animal by euthanasia if in the opinion of the Deputy Administrator the circumstances warrant such action.

(b) In the event that the Veterinary Services representative is unable to locate or notify the dealer, exhibitor, operator of an auction sale, or research facility as required in this section, the Veterinary Services representative shall contact a local police or law officer to accompany him to the premises and shall provide for adequate veterinary care when necessary to alleviate the animal's suffering or, if in the opinion of the Deputy Administrator the condition of the animal cannot be corrected by veterinary care, the Veterinary Services representative shall confiscate and destroy the animal by euthanasia with such costs as may be incurred to be borne by the dealer, exhibitor, operator of an auction sale, or research facility.

(c) Prior to making any decision regarding the destruction of any animal of a species designated by the Department of the Interior or the International Union for the Conservation of Nature and Natural Resources as an endangered species, the Deputy Administrator shall, when possible in his judgment, consult with representatives of said Department and the International Union for the Conservation of Nature and Natural Resources.

§ 2.130 Minimum age requirements.

No dog or cat shall be delivered by any person to any carrier or intermediate handler for transportation, in commerce, except to a registered research facility, unless such dog or cat is at least eight (8) weeks of age and has been weaned.

[42 FR 31029, June 17, 1977]

PART 3—STANDARDS

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AUTHORITY: Secs. 12 and 13, 80 Stat. 351 and 352, as amended, 7 U.S.C. 2142 and 2143, unless otherwise noted.

SOURCE: 32 FR 3273, Feb. 24, 1967, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

Subpart A—Specifications for the Humane Handling, Care, Treatment, and Transportation of Dogs and Cats

FACILITIES AND OPERATING STANDARDS

§ 3.1 Facilities, general.

(a) *Structural strength.* Indoor and outdoor housing facilities for dogs or cats shall be structurally sound and shall be maintained in good repair, to protect the animals from injury, to contain the animals, and to restrict the entrance of other animals.

(b) *Water and electric power.* Reliable and adequate electric power, if required to comply with other provisions of this subpart, and adequate potable water shall be available.

(c) *Storage.* Supplies of food and bedding shall be stored in facilities which adequately protect such supplies against infestation or contamination by vermin. Refrigeration shall be provided for supplies of perishable food.

(d) *Waste disposal.* Provisions shall be made for the removal and disposal of animal and food wastes, bedding, dead animals, and debris. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, and disease hazards.

(e) *Washrooms and sinks.* Facilities, such as washrooms, basins, or sinks, shall be provided to maintain cleanliness among animal caretakers.

[32 FR 3273, Feb. 24, 1967, as amended at 44 FR 63492, Nov. 2, 1979]

§ 3.2 Facilities, indoor.

(a) *Heating.* Indoor housing facilities for dogs or cats shall be sufficiently heated when necessary to protect the dogs or cats from cold, and to provide for their health and comfort. The ambient temperature shall not be allowed to fall below 50° F. for dogs and cats not acclimated to lower temperatures.

(b) *Ventilation.* Indoor housing facilities for dogs or cats shall be adequately ventilated to provide for the health and comfort of the animals at all times. Such facilities shall be provided with fresh air either by means of windows, doors, vents, or air conditioning and shall be ventilated so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans and vents or air conditioning, shall be provided when the ambient temperature is 85° F. or higher.

(c) *Lighting.* Indoor housing facilities for dogs or cats shall have ample light, by natural or artificial means, or both, of good quality and well distributed. Such lighting shall provide uniformly distributed illumination of sufficient light intensity to permit routine inspection and cleaning during the entire working period. Primary enclosures shall be so placed as to protect the dogs or cats from excessive illumination.

(d) *Interior surfaces.* The interior building surfaces of indoor housing facilities shall be constructed and maintained so that they are substantially impervious to moisture and may be readily sanitized.

(e) *Drainage.* A suitable method shall be provided to rapidly eliminate excess water from indoor housing facilities. If drains are used, they shall be properly constructed and kept in good repair to avoid foul odors therefrom. If closed drainage systems are used, they shall be equipped with traps and so installed as to prevent any backup of sewage onto the floor of the room.

§ 3.3 Facilities, outdoor.

(a) *Shelter from sunlight.* When sunlight is likely to cause overheating or discomfort, sufficient shade shall be provided to allow all dogs and cats kept outdoors to protect themselves from the direct rays of the sun.

(b) *Shelter from rain or snow.* Dogs and cats kept outdoors shall be provided with access to shelter to allow them to remain dry during rain or snow.

(c) *Shelter from cold weather.* Shelter shall be provided for all dogs and cats kept outdoors when the atmospheric temperature falls below 50° F. Sufficient clean bedding material or other means of protection from the weather elements shall be provided when the ambient temperature falls below that temperature to which a dog or cat is acclimated.

(d) *Drainage.* A suitable method shall be provided to rapidly eliminate excess water.

§ 3.4 Primary enclosures.

All primary enclosures for dogs and cats shall conform to the following requirements:

(a) *General*—(1) *Requirements for primary enclosures for dogs and cats.* (i) Primary enclosures shall be structurally sound and maintained in good repair to protect the dogs and cats from injury, to contain them, and to keep predators out.

(ii) Primary enclosures shall be constructed and maintained so as to enable the dogs and cats to remain dry and clean.

(iii) Primary enclosures shall be constructed and maintained so that the dogs or cats contained therein have convenient access to clean food and water as required in this subpart.

(iv) The floors of the primary enclosures shall be constructed so as to protect the dogs' and cats' feet and legs from injury.

(2) *Additional requirements for primary enclosures housing cats.* (i) In all enclosures having a solid floor, a receptacle containing sufficient clean litter shall be provided to contain excreta.

(ii) Each primary enclosure shall be provided with a solid resting surface or surfaces which, in the aggregate, shall be of adequate size to comfortably hold all occupants of the primary enclosure at the same time. Such resting surface or surfaces shall be elevated in primary enclosures housing two or more cats.

(b) *Space requirements*—(1) *Dogs and cats.* Primary enclosures shall be constructed and maintained so as to provide sufficient space to allow each dog and cat to turn about freely and to easily stand, sit and lie in a comfortable normal position.

(2) *Dogs.* (i) In addition to the provisions of paragraph (b) (1) of this section, each dog housed in any primary enclosure shall be provided a minimum square footage of floor space equal to the mathematical square of the sum of the length of the dog in inches, as measured from the tip of its nose to the base of its tail, plus 6 inches, expressed in square feet.[1] Not more than 12 adult nonconditioned dogs shall be housed in the same primary enclosure.

(ii) *Dog houses with chains.* If dog houses with chains are used as primary enclosures for dogs kept outdoors, the chains used shall be so placed or attached that they cannot become entangled with the chains of other dogs or any other objects. Such chains shall be of a type commonly used for the size dog involved and shall be attached to the dog by means of a well fitted collar. Such chains shall be at least three times the length of the dog as measured from the tip of its nose to the base of its tail and shall allow the dog convenient access to the dog house.

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[1] This requirement may be computed by using the following equation: (length of dog in inches+6)×(length of dog in inches+6) =Required area in square inches/144=Required square feet of floor space.

(3) *Cats.* In addition to the provisions of paragraph (b)(1) of this section each adult cat housed in any primary enclosure shall be provided a minimum of 2½ square feet of floor space. Not more than 12 adult nonconditioned cats shall be housed in the same primary enclosure.

ANIMAL HEALTH AND HUSBANDRY STANDARDS

§ 3.5 Feeding.

(a) Dogs and cats shall be fed at least once each day except as otherwise might be required to provide adequate veterinary care. The food shall be free from contamination, wholesome, palatable, and of sufficient quantity and nutritive value to meet the normal daily requirements for the condition and size of the dog or cat.

(b) Food receptacles shall be accessible to all dogs or cats and shall be located so as to minimize contamination by excreta. Feeding pans shall be durable and kept clean. The food receptacles shall be sanitized at least once every 2 weeks. Disposable food receptacles may be used but must be discarded after each feeding. Self feeders may be used for the feeding of dry food, and they shall be sanitized regularly to prevent molding, deterioration or caking of feed.

§ 3.6 Watering.

If potable water is not accessible to the dogs and cats at all times, potable liquids shall be offered to such animals at least twice daily for periods of not less than 1 hour, except as might otherwise be required to provide adequate veterinary care. Watering receptacles shall be kept clean and shall be sanitized at least once every 2 weeks.

§ 3.7 Sanitation.

(a) *Cleaning of primary enclosures.* Excreta shall be removed from primary enclosures as often as necessary to prevent contamination of the dogs or cats contained therein and to reduce disease hazards and odors. When a hosing or flushing method is used for cleaning a primary enclosure commonly known as a cage, any dog contained therein shall be removed from such enclosure during the cleaning process, and adequate measures shall be taken to protect the animals in other such enclosures from being contaminated with water and other wastes.

(b) *Sanitization of primary enclosures.* (1) Prior to the introduction of nonconditioned dogs or cats into empty primary enclosures previously occupied, such enclosures shall be sanitized in the manner provided in paragraph (b)(3) of this section.

(2) Primary enclosures for dogs or cats shall be sanitized often enough to prevent an accumulation of debris or excreta, or a disease hazard: *Provided, however,* That such enclosures shall be sanitized at least once every 2 weeks in the manner provided in paragraph (b)(3) of this section.

(3) Cages, rooms and hard-surfaced pens or runs shall be sanitized by washing them with hot water (180° F.) and soap or detergent as in a mechanical cage washer, or by washing all soiled surfaces with a detergent solution followed by a safe and effective disinfectant, or by cleaning all soiled surfaces with live steam. Pens or runs using gravel, sand, or dirt shall be sanitized by removing the soiled gravel, sand, or dirt and replacing it as necessary.

(c) *Housekeeping.* Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart. Premises shall remain free of accumulations of trash.

(d) *Pest control.* An effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained.

§ 3.8 Employees.

A sufficient number of employees shall be utilized to maintain the prescribed level of husbandry practices set forth in this subpart. Such practices shall be under the supervision of an animal caretaker who has a background in animal husbandry or care.

§ 3.9 Classification and separation.

Animals housed in the same primary enclosure shall be maintained in compatible groups, with the following additional restrictions:

(a) Females in season (estrus) shall not be housed in the same primary enclosure with males, except for breeding purposes.

(b) Any dog or cat exhibiting a vicious disposition shall be housed individually in a primary enclosure.

(c) Puppies or kittens shall not be housed in the same primary enclosure with adult dogs or cats other than their dams, except when permanently maintained in breeding colonies.

(d) Dogs shall not be housed in the same primary enclosure with cats, nor shall dogs or cats be housed in the same primary enclosure with any other species of animals.

(e) Dogs or cats under quarantine or treatment for a communicable disease shall be separated from other dogs or cats and other susceptible species of animals in such a manner as to minimize dissemination of such disease.

§ 3.10 Veterinary care.

(a) Programs of disease control and prevention, euthanasia, and adequate veterinary care shall be established and maintained under the supervision and assistance of a doctor of veterinary medicine.

(b) Each dog and cat shall be observed daily by the animal caretaker in charge, or by someone under his direct supervision. Sick or diseased, injured, lame, or blind dogs or cats shall be provided with veterinary care or humanely disposed of unless such action is inconsistent with the research purposes for which such animal was obtained and is being held: *Provided, however,* That the provision shall not effect compliance with any State or local law requiring the holding, for a specified period, of animals suspected of being diseased.

(c)(1) In the case of a research facility, the program of adequate veterinary care shall include the appropriate use of anesthetic, analgesic, or tranquilizing drugs, when such use would be proper in the opinion of the attending veterinarian at the research facility. The use of these three classes of drugs shall be in accordance with the currently accepted veterinary medical practice as cited in appropriate professional journals or reference guides which shall produce in the individual subject animal a high level of tranquilization, anesthesia, or analgesia consistent with the protocol or design of the experiment.

(2) It shall be incumbent upon each research facility through its animal care committee and/or attending veterinarian to provide guidelines and consultation to research personnel with respect to the type and amount of tranquilizers, anesthetics, or analgesics recommended as being appropriate for each species of animal used by that institution.

(3) The use of these three classes of drugs shall effectively minimize the pain and discomfort of the animals while under experimentation.

[32 FR 3273, Feb. 24, 1967, as amended at 36 FR 24925, Dec. 24, 1971]

TRANSPORTATION STANDARDS

AUTHORITY: Sections 3.11 through 3.17 issued under secs. 3, 5, 6, 10, 11, 14, 16, 17, 21; 80 Stat. 353; 84 Stat. 1561, 1562, 1563, 1564; 90 Stat. 418, 419, 420, 423 (7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2144, 2146, 2147, 2151); 37 FR 28464, 28477, 38 FR 19141.

SOURCE: Sections 3.11 through 3.17 appear at 42 FR 31561, June 21, 1977, unless otherwise noted.

§ 3.11 Consignments to carriers and intermediate handlers.

(a) Carriers and intermediate handlers shall not accept any live dog or cat presented by any dealer, research facility, exhibitor, operator of an auction sale or other person, or any department, agency, or instrumentality of the United States or any State or local government for shipment, in commerce, more than 4 hours prior to the scheduled departure of the primary conveyance on which it is to be transported: *Provided, however,* That the carrier or intermediate handler and any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or any State or local government may mutually agree to extend the time of acceptance to not more than 6 hours if specific prior scheduling of the animal shipment to destination has been made.

(b) Any carrier or intermediate handler shall only accept for transportation or transport, in commerce, any live dog or cat in a primary enclosure which conforms to the requirements set forth in § 3.12 of the standards: *Provided, however,* That any carrier or intermediate handler may accept for transportation or transport, in commerce, any live dog or cat consigned by any department, agency, or instrumentality of the United States having laboratory animal facilities or exhibiting animals, or any licensed or registered dealer, research facility, exhibitor, or operator of an auction sale, if such consignor furnishes to the carrier or intermediate handler a certificate, signed by the consignor, stating that the primary enclosure complies with § 3.12 of the standards, unless such primary enclosure is obviously defective or damaged and it is apparent that it cannot reasonably be expected to contain the live dog or cat without causing suffering or injury to such live dog or cat. A copy of such certificate shall accompany the shipment to destination. The certificate shall include at least the following information:

(1) Name and address of the consignor;

(2) Tag number or tattoo assigned to each dog or cat pursuant to §§ 2.50 and 2.54 of the regulations;

(3) A certifying statement (e.g., "I hereby certify that the ——— (number) primary enclosure(s) which are used to transport the animal(s) in this shipment complies (comply) with USDA standards for primary enclosures (9 CFR Part 3)."); and

(4) The signature of the consignor, and date.

(c) Carriers or intermediate handlers whose facilities fail to meet the minimum temperature allowed by the standards, may accept for transportation or transport, in commerce, any live dog or cat consigned by any department, agency, or instrumentality of the United States or of any State or local government, or by any person (including any licensee or registrant under the Act, as well as any private individual) if the consignor furnishes to the carrier or intermediate handler a certificate executed by a veterinarian accredited by this Department pursuant to Part 160 of this title on a specified date which shall not be more than 10 days prior to delivery of such dog or cat for transportation in commerce, stating that such live dog or cat is acclimated to air temperatures lower than those prescribed in §§ 3.16 and 3.17. A copy of such certificate shall accompany the shipment to destination. The certificate shall include at least the following information:

(1) Name and address of the consignor;

(2) Tag number or tattoo assigned to each dog or cat pursuant to §§ 2.50 and 2.54 of the regulations;

(3) A certifying statement (e.g., "I hereby certify that the animal(s) in this shipment is (are), to the best of my knowledge, acclimated to air temperatures lower than 7.2° C. (45° F.)."); and

(4) The signature of the USDA accredited veterinarian, assigned accreditation number and date.

(d) Carriers and intermediate handlers shall attempt to notify the consignee at least once in every 6 hour period following the arrival of any live dog or cat at the animal holding area of the terminal cargo facility. The time, date, and method of each attempted notification and the final notification to the consignee and the name of the person notifying the consignee shall be recorded on the copy of the shipping document retained by the carrier of intermediate handler and on a copy of the shipping document accompanying the animal shipment.

[42 FR 31561, June 21, 1977, as amended at 43 FR 21161, May 16, 1978; 44 FR 63492, Nov. 2, 1979]

§ 3.12 Primary enclosures used to transport live dogs and cats.

No dealer, research facility, exhibitor, or operator of an auction sale shall offer for transportation or tranport, in commerce, any live dog or cat in a primary enclosure which does not conform to the following requirements:

(a) Primary enclosures, such as compartments, transport cages, cartons, or crates, used to transport live dogs and cats shall be constructed in such a manner that:

(1) The structural strength of the enclosure shall be sufficient to contain the live dogs and cats and to withstand the normal rigors of transportation;

(2) The interior of the enclosure shall be free from any protrusions that could be injurious to the live dogs or cats contained therein;

(3) The openings of such enclosures are easily accessible at all times for emergency removal of the live dogs or cats;

(4) Except as provided in paragraph (h) of this section, such primary enclosures shall comply with one of the following requirements:

(i) There are ventilation openings located on two opposing walls of the primary enclosure and the ventilation openings on each of the two walls shall be at least 16 percent of the surface area of each such wall and the total combined surface area of the ventilation openings shall be at least 14 percent of the total combined surface area of all the walls of the primary enclosure, or

(ii) There are ventilation openings on three walls of the primary enclosure and the ventilation openings on two opposing walls shall be at least 8 percent of the total surface area of the two walls and the ventilation openings on the third wall of the primary enclosure shall be at least 50 percent of the total surface area of such wall and the total combined surface area of the ventilation openings shall be at least 14 percent of the total combined surface area of all the walls of the primary enclosure, or

(iii) There are ventilation openings located on all four walls of the primary enclosure and the ventilation openings on each of the four walls shall be at least 8 percent of the total surface of each wall and the total combined surface area of the ventilation openings shall be at least 14 percent of the total combined surface area of all the walls of the primary enclosure: *Provided, however,* That at least one-third of the total minimum area required for ventilation of the primary enclosure shall be located on the lower one-half of the primary enclosure and at least one-third of the total minimum area required for ventilation of the primary enclosure shall be located on the upper one-half of the primary enclosure;

(5) Except as provided in paragraph (h) of this section, projecting rims or other devices shall be on the exterior of the outside walls with any ventilation openings to prevent obstruction of the ventilation openings and to provide a minimum air circulation space of 1.9 centimeters (.75 inches) between the primary enclosure and any adjacent cargo or conveyance wall; and

(6) Except as provided in paragraph (h) of this section, adequate handholds or other devices for lifting shall be provided on the exterior of the primary enclosure to enable the primary enclosure to be lifted without tilting and to ensure that the person handling the primary enclosure will not be in contact with the dog or cat.

(b) Live dogs or cats transported in the same primary enclosure shall be of the same species and maintained in compatible groups. Puppies or kittens shall not be transported in the same primary enclosure with adult dogs or cats, other than their dams.

(c) Primary enclosures used to transport live dogs and cats shall be large enough to ensure that each animal contained therein has sufficient space to turn about freely in a standing position using normal body movements, to stand and sit erect, and to lie in a natural position.

(d) A maximum of one live dog or cat, 6 months or more of age, or a maximum of one live puppy, 8 weeks to 6 months of age and weighing over 9 kilograms (20 pounds), shall be transported in a primary enclosure. Two live puppies and kittens, 8 weeks to 6 months of age, but not weighing over 9 kilograms (20 pounds) each and of comparable size, may be carried in the same primary enclosure. Weaned live puppies or kittens less than 8 weeks of age and of comparable size, or puppies or kittens which are less than 8 weeks of age and littermates accompanied by their dam, may be shipped in the same primary enclosure to research laboratories.

(e) Primary enclosures used to transport live dogs and cats as provided in this section shall have solid bottoms to prevent leakage in shipment and shall be cleaned and sanitized in a manner prescribed in § 3.7 of the standards, if previously used. Such primary enclosures shall contain clean litter of a suitable absorbent material, which is safe and nontoxic to the dogs and cats, in sufficient quanitity to aborb and cover excreta, unless the dogs or cats are on wire or other nonsolid floors.

(f) Primary enclosures used to transport live dogs and cats, except where such primary enclosures are permanently affixed in the animal cargo space of the primary conveyance, shall be clearly marked on top and on one or more sides with the words "Live Animals" in letters not less then 2.5 centimeters (1 inch) in height, and with arrows or other markings, to indicate the correct upright position of the container.

(g) Documents accompanying the shipment shall be attached in an easily accessible manner to the outside of a primary enclosure which is part of such shipment.

(h) When a primary enclosure is permanently affixed within the animal cargo space of the primary conveyance so that the front opening is the only source of ventilation for such primary enclosure, the front opening shall open directly to the outside or to an unobstructed aisle or passageway within the primary conveyance. Such front ventilation opening shall be at least 90 percent of the total surface area of the front wall of the primary enclosure and covered with bars, wire mesh or smooth expanded metal.

(7 U.S.C. 2131-2156; 42 FR 31562, June 21, 1977, as amended at 43 FR 21162, May 16, 1978; 45 FR 15880, March 11, 1980)

[42 FR 31561, June 21, 1977, as amended at 43 FR 21162, May 16, 1978; 44 FR 63492, Nov. 2, 1979; 45 FR 37618, June 3, 1980]

§ 3.13 Primary conveyances (motor vehicle, rail, air, and marine).

(a) The animal cargo space of primary conveyances used in transporting live dogs and cats shall be designed and constructed to protect the health, and ensure the safety and comfort of the dogs and cats contained therein at all times.

(b) The animal cargo space shall be constructed and maintained in a manner to prevent the ingress of engine exhaust fumes and gases from the primary conveyance during transportation in commerce.

(c) No live dog or cat shall be placed in an animal cargo space that does not have a supply of air sufficient for normal breathing for each live animal contained therein, and the primary enclosures shall be positioned in the animal cargo space in such a manner that each dog or cat has access to sufficient air for normal breathing.

(d) Primary enclosures shall be positioned in the primary conveyance in such a manner that in an emergency the live dogs and cats can be removed from the primary conveyance as soon as possible.

(e) The interior of the animal cargo space shall be kept clean.

(f) Live dogs and cats shall not be transported with any material, substance (e.g., dry ice) or device which may reasonably be expected to be injurious to the health and well-being of the dogs and cats unless proper precaution is taken to prevent such injury.

§ 3.14 Food and water requirements.

(a) All live dogs or cats shall be offered potable water within 4 hours prior to being transported in commerce. Any live dogs or cats less than 16 weeks of age being offered to any carrier for transportation in commerce shall be offered at least 60 cubic centimeters (ccs.) (approximately 2 ounces) of potable water within 4 hours prior to being so offered for transportation in commerce. Dealers, exhibitors, research facilities and operators of auction sales shall provide potable water to all live dogs and cats transported in their own primary conveyance at least every 12 hours after such transportation is initiated, and carriers and intermediate handlers shall provide potable water to all live dogs and cats at least every 12 hours after acceptance for transportation in commerce.

(b) Each live dog and cat over 16 weeks of age shall be fed at least once in each 24 hour period. Live puppies and kittens less then 16 weeks of age shall have food made available to them at least every 12 hours. The time periods provided for in this paragraph shall apply to carriers and intermediate handlers after acceptance of any live dog or cat for transportation, in commerce, and shall apply to dealers, exhibitors, research facilities, and operators of auction sales who transport live dogs and cats in their own primary conveyance after such transportation in initiated.

(c) Any dealer, research facility, exhibitor or operator of an auction sale offering any live dog or cat to any carrier or intermediate handler for transportation in commerce shall affix to the outside of the primary enclosure used for transporting such dog or cat, written instructions concerning the food and water requirements of such dog or cat while being transported.

(d) No carrier or intermediate handler shall accept any live dog or cat for transportation in commerce unless written instructions concerning the food and water requirements of such dog or cat while being so transported is affixed to the outside of its primary enclosure.

§ 3.15 Care in transit.

(a) During surface transportation it shall be the responsibility of the driver or other employee to visually observe the live dogs or cats as frequently as circumstances may dictate, but not less than once every 4 hours, to assure that they are receiving sufficient air for normal breathing, their ambient temperatures are within the prescribed limits, all other applicable standards are being complied with and to determine whether any of the live dogs or cats are in obvious physical distress and to provide any needed veterinary care as soon as possible. When transported by air, live dogs and cats shall be visually observed by the carrier as frequently as circumstances may dictate, but not less than once every 4 hours, if the animal cargo space is accessible during flight. If the animal cargo space is not accessible during flight, the carrier shall visually observe the live dogs or cats whenever loaded and unloaded and whenever the animal cargo space is otherwise accessible to assure that they are receiving sufficient air for normal breathing, their ambient temperatures are within the prescribed limits, all other applicable standards are being complied with and to determine whether and such live dogs or cats are in obvious physical distress. The carrier shall provide any needed veterinary care as soon as possible. No dog or cat in obvious physical distress shall be transported in commerce.

(b) During the course of transportation, in commerce, live dogs or cats shall not be removed from their primary enclosures unless placed in other primary enclosures or facilities conforming to the requirements provided in this subpart.

§ 3.16 Terminal facilities.

Carriers and intermediate handlers shall not commingle live animal shipments with inanimate cargo. All animal holding areas of a terminal facility of any carrier or intermediate handler wherein live animal shipments are maintained shall be cleaned and sanitized in a manner prescribed in § 3.7 of the standards often enough to prevent an accumulation of debris or excreta, to minimize vermin infestation and to prevent a disease hazard. An effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained for all animal holding areas. Any animal holding area containing live dogs or cats shall be provided with fresh air by means of windows, doors, vents, or air conditioning and may be ventilated or air circulated by means of fans, blowers, or an air conditioning system so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans and vents or fans or blowers or air conditioning shall be used for any animal holding area containing live dogs and cats when the air temperature within such animal holding area is 23.9° C. (75.° F.) or higher. The air temperature around any live dog or cat in any animal holding area shall not be allowed to fall below 7.2° C. (45° F.) nor be allowed to exceed 29.5° C. (85° F.) at any time: *Provided, however,* That no live dog or cat shall be subjected to air temperatures around any such dog or cat in excess of 23.9° C. (75° F.) for more than 4 hours at any time. To ascertain compliance with the provisions of this paragraph, the air temperature around any live dog or cat shall be measured and read outside the primary enclosure which contains such dog or cat at a distance not to exceed .91 meters (3 feet) from any one of the external walls of the primary enclosure and on a level parallel to the bottom of such primary enclosure at a point which approximates half the distance between the top and bottom of such primary enclosure.

[43 FR 56215, Dec. 1, 1978]

§ 3.17 Handling.

(a) Carriers and intermediate handlers shall move live dogs and cats from the animal holding area of the terminal facility to the primary conveyance and from the primary conveyance to the animal holding area of the terminal facility as expeditiously as possible. Carriers and intermediate handlers holding any live dog or cat in an animal holding area of a terminal facility or in transporting any live dog or cat from the animal holding area of the terminal facility to the primary conveyance and from the primary conveyance to the animal holding area of the terminal facility, including loading and unloading procedures, shall provide the following:

(1) *Shelter from sunlight.* When sunlight is likely to cause overheating or discomfort, sufficient shade shall be provided to protect the live dogs and cats from the direct rays of the sun and such live dogs or cats shall not be subjected to surrounding air temperatures which exceed 29.5° C. (85° F.), and which shall be measured and read in the manner prescribed in §3.16 of this part, for a period of more than 45 minutes.

(2) *Shelter from rain or snow.* Live dogs and cats shall be provided protection to allow them to remain dry during rain or snow.

(3) *Shelter from cold weather.* Transporting devices shall be covered to provide protection for live dogs and cats when the outdoor air temperature falls below 10° C. (50° F.), and such live dogs or cats shall not be subjected to surrounding air temperatures which fall below 7.2° C. (45° F.), and which shall be measured and read in the manner prescribed in § 3.16 of this part, for a period of more than 45 minutes unless such dogs or cats are accompanied by a certificate of acclimation to lower temperatures as prescribed in § 3.11(c).

(b) Care shall be exercised to avoid handling of the primary enclosure in such a manner that may cause physical or emotional trauma to the live dog or cat contained therein.

(c) Primary enclosures used to transport any live dog or cat shall not be tossed, dropped, or needlessly tilted and shall not be stacked in a manner which may reasonably be expected to result in their falling.

[43 FR 21162, May 16, 1978, as amended at 43 FR 56215, Dec. 1, 1978]

Subpart B—Specifications for the Humane Handling, Care, Treatment, and Transportation of Guinea Pigs and Hamsters

FACILITIES AND OPERATING STANDARDS

§ 3.25 Facilities, general.

(a) *Structural strength.* Indoor and outdoor housing facilities for guinea pigs or hamsters shall be structurally sound and shall be maintained in good repair, to protect the animals from injury, to contain the animals, and to restrict the entrance of other animals.

(b) *Water and electric power.* Reliable and adequate electric power, if required to comply with other provisions of this subpart, and adequate potable water shall be available.

(c) *Storage.* Supplies of food and bedding shall be stored in facilities which adequately protect such supplies against spoilage or deterioration and infestation or contamination by vermin. Food supplies shall be stored in containers with tightly fitting lids or covers or in the original containers as received from the commercial sources of supply. Refrigeration shall be provided for supplies of perishable food.

(d) *Waste disposal.* Provisions shall be made for the removal and disposal of animal and food wastes, bedding, dead animals, and debris. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, and disease hazards.

(e) *Washroom and sinks.* Facilities, such as washrooms, basins, or sinks, shall be provided to maintain cleanliness among animal caretakers.

[32 FR 3273, Feb. 24, 1967, as amended at 44 FR 63492, Nov. 2, 1979]

§ 3.26 Facilities, indoor.

(a) *Heating.* Indoor housing facilities for guinea pigs or hamsters shall be sufficiently heated when necessary to protect the animals from the cold, and to provide for their health and comfort. The ambient temperature shall not be allowed to fall below 60° F. nor to exceed 85° F.

(b) *Ventilation.* Indoor housing facilities for guinea pigs or hamsters shall be adequately ventilated to provide for the health and comfort of the animals at all times. Such facilities shall be provided with fresh air either by means of windows, doors, vents, or air conditioning, and shall be ventilated so as to minimize drafts, odors, and moisture condensation. The ambient temperature shall not be allowed to rise above 85° F.

(c) *Lighting.* Indoor housing facilities for guinea pigs or hamsters shall have ample light, by natural or artificial means, or both, of good quality and well distributed. Such lighting shall provide uniformly distributed illumination of sufficient light intensity to permit routine inspection and cleaning during the entire working period. Primary enclosures shall be so placed as to protect the guinea pigs or hamsters from excessive illumination.

(d) *Interior surfaces.* The interior building surfaces of indoor housing facilities shall be constructed and maintained so that they are substantially impervious to moisture and may be readily sanitized.

§ 3.27 Facilities, outdoor.

(a) Hamsters shall not be housed in outdoor facilities.

(b) Guinea pigs shall not be housed in outdoor facilities unless such facilities are located in an appropriate climate and prior approval for such outdoor housing is obtained from the Deputy Administrator.

§ 3.28 Primary enclosures.

All primary enclosures for guinea pigs and hamsters shall conform to the following requirements:

(a) *General.* (1) Primary enclosures shall be structurally sound and maintained in good repair to protect the guinea pigs and hamsters from injury. Such enclosures, including their racks, shelving and other accessories, shall be constructed of smooth material substantially impervious to liquids and moisture.

(2) Primary enclosures shall be constructed and maintained so that the guinea pigs or hamsters contained therein have convenient access to clean food and water as required in this subpart.

(3) Primary enclosures having a solid floor shall be provided with clean bedding material.

(4) Primary enclosures equipped with mesh or wire floors shall be so constructed as to allow feces to pass through the spaces of the mesh or wire: *Provided, however,* That such floors shall be constructed so as to protect the animals' feet and legs from injury.

(b) *Space requirements*—(1) *Guinea pigs and hamsters.* Primary enclosures shall be constructed and maintained so as to provide sufficient space for each animal contained therein to make normal postural adjustments with adequate freedom of movement.

(2) *Guinea pigs.* In addition to the provisions of paragraph (b)(1) of this section, the following space requirements are applicable to primary enclosures for guinea pigs:

(i) The interior height of any primary enclosure used to confine guinea pigs shall be at least 6½ inches.

(ii) Each guinea pig housed in a primary enclosure shall be provided a minimum amount of floor space in accordance with the following table:

Weight or stage of maturity	Minimum space per guinea pig (square inches)
Weaning to 350 grams	60
350 grams or more	90
Breeders	180

(3) *Hamsters.* In addition to the provisions of paragraph (b)(1) of this section, the following space requirements are applicable to primary enclosures for hamsters:

(i) The interior height of any primary enclosure used to confine hamsters shall be at least 5½ inches, except that in the case of dwarf hamsters, such interior height shall be at least 5 inches.

(ii) A nursing female hamster, together with her litter, shall be housed in a primary enclosure which contains no other hamsters and which provides at least 121 square inches of floor space: *Provided, however,* That in the case of dwarf hamsters such floor space shall be at least 25 square inches.

(iii) The minimum amount of floor space per individual hamster and the maximum number of hamsters allowed in a single primary enclosure, except as provided for nursing females in paragraph (b)(3)(ii) of this section, shall be in accordance with the following table:

Age	Minimum space per hamster (square inches)		Maximum population per enclosure
	Dwarf	*Other*	
Weaning to 5 wks	5.0	10.0	20
5 to 10 wks	7.5	12.5	16
10 wks. or more	9	15.0	13

ANIMAL HEALTH AND HUSBANDRY STANDARDS

§ 3.29 Feeding.

(a) Guinea pigs and hamsters shall be fed each day except as otherwise might be required to provide adequate veterinary care. The food shall be free from contamination, wholesome, palatable and of sufficient quantity and nutritive value to meet the normal daily requirements for the condition and size of the guinea pig or hamster.

(b) Food comprising the basic diet shall be at least equivalent in quality and content to pelleted rations produced commercially and commonly available from feed suppliers.

(c) The basic diet of guinea pigs and hamsters may be supplemented with good quality fruits or vegetables consistent with their individual dietary requirements.

(d) Food receptacles, if used, shall be accessible to all guinea pigs or hamsters in a primary enclosure and shall be located so as to minimize contamination by excreta. All food receptacles shall be kept clean and shall be sanitized at least once every 2 weeks. If self-feeders are used for the feeding of pelleted feed, measures must be taken to prevent molding, deterioration or caking of the feed. Hamsters may be fed pelleted feed on the floor of a primary enclosure.

(e) Fruit or vegetable food supplements may be placed upon the bedding within the primary enclosure: *Provided, however,* That the uneaten portion of such supplements and any bedding soiled as a result of such feeding practices shall be removed from the primary enclosure when such uneaten supplements accumulate or such bedding becomes soiled to a degree that might be harmful or uncomfortable to animals therein.

§ 3.30 Watering.

Unless food supplements consumed by guinea pigs or hamsters supply them with their normal water requirements, potable water shall be provided daily except as might otherwise be required to provide adequate veterinary care. Open containers used for dispensing water to guinea pigs or hamsters shall be so placed in or attached to the primary enclosure as to minimize contamination from excreta. All watering receptacles shall be sanitized when dirty: *Provided, however,* That such receptacles shall be sanitized at least once every 2 weeks.

§ 3.31 Sanitation.

(a) *Cleaning and sanitation of primary enclosures.* (1) Primary enclosures shall be cleaned and sanitized often enough to prevent an accumulation of excreta or debris: *Provided, however,* That such enclosures shall be sanitized at least once every 2 weeks in the manner provided in paragraph (a)(4) of this section.

(2) In the event a primary enclosure becomes soiled or wet to a degree that might be harmful or uncomfortable to the animals therein due to leakage of the watering system, discharges from dead or dying animals, spoiled perishable foods, or moisture condensation, the guinea pigs or hamsters shall be transferred to clean primary enclosures.

(3) Prior to the introduction of guinea pigs or hamsters into empty primary enclosures previously occupied, such enclosures shall be sanitized in the manner provided in paragraph (a)(4) of this section.

(4) Primary enclosures for guinea pigs or hamsters shall be sanitized by washing them with hot water (180° F.) and soap or detergent as in a mechanical cage washer, or by washing all soiled surfaces with a detergent solution followed by a safe and effective disinfectant, or by cleaning all soiled surfaces with live steam.

(b) *Housekeeping.* Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart. Premises shall remain free of accumulations of trash.

(c) *Pest control.* An effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained.

§ 3.32 Employees.

A sufficient number of employees shall be utilized to maintain the prescribed level of husbandry practices set forth in this subpart. Such practices shall be under the supervision of an animal caretaker who has a background in animal husbandry or care.

§ 3.33 Classification and separation.

Animals housed in the same primary enclosure shall be maintained in compatible groups, with the following additional restrictions:

(a) Except where harem breeding is practiced, preweanling guinea pigs shall not be housed in the same primary enclosure with adults other than their parents.

(b) Guinea pigs shall not be housed in the same primary enclosure with hamsters, nor shall guinea pigs or hamsters be housed in the same primary enclosure with any other species of animals.

(c) Guinea pigs or hamsters under quarantine or treatment for a communicable disease shall be separated from other guinea pigs or hamsters and other susceptible species of animals in such a manner as to minimize dissemination of such disease.

§ 3.34 Veterinary care.

(a) Programs of disease control and prevention, euthanasia, and adequate veterinary care shall be established and maintained under the supervision and assistance of a doctor of veterinary medicine.

(b) Each guinea pig and hamster shall be observed at least every 48 hours by the animal caretaker in charge, or by someone under his direct supervision, for evidence of disease or injury. Sick or diseased, injured, lame, or blind guinea pigs or hamsters shall be provided with veterinary care or humanely disposed of unless such action is inconsistent with the research purposes for which such animal was obtained and is being held.

(c)(1) In the case of a research facility, the program of adequate veterinary care shall include the appropriate use of anesthetic, analgesic, or tranquilizing drugs, when such use would be proper in the opinion of the attending veterinarian at the research facility. The use of these three classes of drugs shall be in accordance with the currently accepted veterinary medical practice as cited in appropriate professional journals or reference guides which shall produce in the individual object animal a high level of tranquilization, anesthesia, or analgesia consistent with the protocol or design of the experiment.

(2) It shall be incumbent upon each research facility through its animal care committee and/or attending veterinarian to provide guidelines and consultation to research personnel with respect to the type and amount of tranquilizers, anesthetics, or analgesics recommended as being appropriate for each species of animal used by that institution.

(3) The use of these three classes of drugs shall effectively minimize the pain and discomfort of the animals while under experimentation.

[32 FR 3273, Feb. 24, 1967, as amended at 36 FR 24925, Dec. 24, 1971]

TRANSPORTATION STANDARDS

AUTHORITY: Sections 3.35 through 3.41 issued under secs. 3, 5, 6, 10, 11, 14, 16, 17, 21; 80 Stat. 353; 84 Stat. 1561, 1562, 1563, 1564; 90 Stat. 418, 419, 420, 423; (7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2144, 2146, 2147, 2151); 37 FR 28464, 28477, 38 FR 19141.

SOURCE: Sections 3.35 through 3.41 appear at 42 FR 31563, June 21, 1977, unless otherwise noted.

§ 3.35 Consignments to carriers and intermediate handlers.

(a) Carriers and intermediate handlers shall not accept any live guinea pig or hamster presented by any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or any State or local govenment for shipment, in commerce, more than 4 hours prior to the scheduled departure of the primary conveyance on which it is to be transported: *Provided, however*, That the carrier or intermediate handler and any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or any State or local government may mutually agree to extend the time of acceptance to not more than 6 hours if specific prior scheduling of the animal shipment to destination has been made.

(b) Any carrier or intermediate handler shall only accept for transportation or transport, in commerce any live guinea pig or hamster in a primary enclosure which conforms to the requirements set forth in § 3.36 of the standards: *Provided, however*, That any carrier or intermediate handler may accept for transportation or transport, in commerce, any live guinea pig or hamster consigned by any department, agency, or instrumentality of the United States having laboratory animal facilities or exhibiting animals, or any licensed or registered dealer, research facility, exhibitor, or operator of an auction sale, if such consignor furnishes to the carrier or intermediate handler a certificate, signed by the consignor, stating that the primary enclosure complies with § 3.36 of the standards, unless such primary enclosure is obviously defective or damaged and it is apparent that it cannot reasonably be expected to contain the live guinea pig or hamster without causing suffering or injury to such live guinea pig or hamster. A copy of such certificate shall accompany the shipment to destination. The certificate of compliance shall include at least the following information:

(1) Name and address of the consignor;

(2) The number of guinea pigs or hamsters in the primary enclosure(s);

(3) A certifying statement (e.g., "I hereby certify that the —— (number) primary enclosure(s) which are used to transport the animal(s) in this shipment complies (comply) with USDA standards for primary enclosures (9 CFR Part 3)."); and

(4) The signature of the consignor, and date.

(c) Carriers or intermediate handlers whose facilities fail to meet the minimum temperature allowed by the standards may accept for transportation or transport, in commerce, any live hamster consigned by any department, agency, or instrumentality of the United States or of any State or local government, or by any person (including any licensee or registrant under the Act, as well as any private individual) if the consignor furnishes to the carrier or intermediate handler a certificate executed by a veterinarian accredited by this Department pursuant to Part 160 of this title on a specified date which shall not be more than 10 days prior to delivery of such hamster for transportation in commerce, stating that such live hamster is acclimated to air temperatures lower than those prescribed in §§ 3.40 and 3.41. A copy of such certificate shall accompany the shipment to destination. The certificate shall include the following information:

(1) Name and address of the consignor;

(2) The number of hamsters in the shipment;

(3) A certifying statement (e.g., "I hereby certify that the animal(s) in this shipment is (are), to the best of my knowledge, acclimated to air temperatures lower than 7.2° C. (45° F.)."); and

(4) The signature of the USDA accredited veterinarian, assigned accreditation number, and date.

(d) Carriers and intermediate handlers shall attempt to notify the consignee at least once in every 6 hour period following the arrival of any live guinea pig or hamster at the animal holding area of the terminal cargo facility. The time, date, and method of each attempted notification and the final notification to the consignee and the name of the person notifying the consignee shall be recorded on the copy of the shipping document retained by the carrier or intermediate handler and on a copy of the shipping document accompanying the animal shipment.

[42 FR 31563, June 21, 1977, as amended at 43 FR 22163, May 16, 1978; 44 FR 63492, Nov. 2, 1979]

§ 3.36 Primary enclosures used to transport live guinea pigs and hamsters.

No dealer, research facility, exhibitor, or operator of an auction sale shall offer for transportation or transport, in commerce, any live guinea pig or hamster in a primary enclosure which does not conform to the following requirements:

(a) Primary enclosures, such as compartments, transport cages, cartons, or crates, used to transport live guinea pigs or hamsters shall be constructed in such a manner that (1) the structural strength of the enclosure shall be sufficient to contain the live guinea pigs or hamsters and to withstand the normal rigors of transportation; (2) the interior of the enclosure shall be free from any protrusions that could be injurious to the live guinea pigs or hamsters contained therein; (3) the inner surfaces of corrugated fiberboard, cardboard, or plastic containers shall be covered or laminated with wire mesh or screen where necessary to prevent escape of the animals; (4) the openings of such enclosures are easily accessible at all times for emergency removal of the live guinea pigs or hamsters; (5) except as provided in paragraph (i) of this section, there are ventilation openings located on two opposite walls of the primary enclosure and the ventilation openings on each such wall shall be at least 16 percent of the total surface area of each such wall, or there are ventilation openings located on all four walls of the primary enclosure and the ventilation openings on each such wall shall be at least 8 percent of the total surface area of each such wall: *Provided, however,* That at least one-third of the total minimum area required for ventilation of the primary enclosure shall be located on the lower one-half of the primary enclosure and at least one-third of the total minimum area required for ventilation of the primary enclosure shall be located on the upper one-half of the primary enclosure; (6) except as provided in paragraph (i) of this section, projecting rims or other devices shall be on the exterior of the outside walls with any ventilation openings to prevent obstruction of the ventilation openings and to provide a minimum air circulation space of 1.9 centimeters (.75 inches) between the primary enclosure and any adjacent cargo or conveyance wall; and (7) except as provided in paragraph (i) of this section, adequate handholds or other devices for lifting shall be provided on the exterior of the primary enclosure to enable the primary enclosure to be lifted without tilting and to ensure that the person handling the primary enclosure will not be in contact with the guinea pigs or hamsters.

(b) Live guinea pigs or hamsters tranported in the same primary enclosure shall be of the same species and maintained in compatible groups.

(c) Primary enclosures used to transport live guinea pigs or hamsters shall be large enough to ensure that each animal contained therein has sufficient space to turn about freely and to make normal postural adjustments.

(d) Not more than 15 live guinea pigs shall be transported in the same primary enclosure. No more than 50 live hamsters shall be transported in the same primary enclosure.

(e) In addition to the other provisions of this section, the following requirements shall also apply to primary enclosures used to transport live guinea pigs or hamsters:

(1) *Guinea pigs.* (i) The interior height of primary enclosures used to tranport live guinea pigs weighing up to 500 grams shall be at least 15.2 centimeters (6 inches) and the interior height of primary enclosures used to transport live guinea pigs weighing over 500 grams shall be at least 17.8 centimeters (7 inches).

(ii) Each live guinea pig transported in a primary enclosure shall be provided a minimum amount of floor space in accordance with the following table:

Minimum space per live guinea pig

Weight (grams)	Square centimeters	Square inches
Up to 350	193.6	30
350 to 600	290.3	45
Over 600	354.8	55

(2) *Hamsters.* (i) The interior height of primary enclosures used to transport live hamsters shall be at least 15.2 centimeters (6 inches) except that in the case of dwarf hamsters such interior height shall be at least 12.7 centimeters (5 inches).

(ii) Each live hamster transported in a primary enclosure shall be provided a minimum amount of floor space in accordance with the following table:

Minimum space per live hamster

Age	Dwarf		Other	
	Square centimeters	Square inches	Square centimeters	Square inches
Weaning to 5 wks	32.2	5.0	45.2	7
5 to 10 wks	48.3	7.5	71.0	11
Over 10 wks	58.1	9.0	96.8	15

(f) Primary enclosures used to transport live guinea pigs or hamsters as provided in this section shall have solid bottoms to prevent leakage in shipment and shall be cleaned and sanitized in a manner prescribed in § 3.31 of the standards, if previously used. Such primary enclosures shall contain clean litter of a suitable absorbent material, which is safe and nontoxic to the guinea pigs or hamsters, in sufficient quantity to absorb and cover excreta, unless the guinea pigs or hamsters are on wire or other nonsolid floors.

(g) Primary enclosures used to transport live guinea pigs or hamsters, except where such primary enclosures are permanently affixed in the animal cargo space of the primary conveyance, shall be clearly marked on top and on one or more sides with the words "Live Animals" in letters not less than 2.5 centimeters (1 inch) in height, and with arrows or other markings, to indicate the correct upright position of the container.

(h) Documents accompanying the shipment shall be attached in an easily accessible manner to the outside of a primary enclosure which is part of such shipment.

(i) When a primary enclosure is permanently affixed within the animal cargo space of the primary conveyance so that the front opening is the only source of ventilation for such primary enclosure, the front opening shall open directly to the outside or to an unobstructed aisle or passageway within the primary conveyance. Such front ventilation opening shall be at least 90 percent of the total surface area of the front wall of the primary enclosure and covered with bars, wire mesh or smooth expanded metal.

[42 FR 31563, June 21, 1977, as amended at 43 FR 21163, May 16, 1978]

§ 3.37 Primary conveyances (motor vehicle, rail, air, and marine).

(a) The animal cargo space of primary conveyances used in transporting live guinea pigs and hamsters shall be designed and constructed to protect the health, and ensure the safety and comfort of the live guinea pigs and hamsters at all times.

(b) The animal cargo space shall be constructed and maintained in a manner to prevent the ingress of engine exhaust fumes and gases from the primary conveyance during transportation in commerce.

(c) No live guinea pig or hamster shall be placed in an animal cargo space that does not have a supply of air sufficient for normal breathing for each live animal contained therein, and the primary enclosures shall be positioned in the animal cargo space in such a manner that each live guinea pig or hamster has access to sufficient air for normal breathing.

(d) Primary enclosures shall be positioned in the primary conveyance in such a manner that in an emergency the live guinea pigs or hamsters can be removed from the primary conveyance as soon as possible.

(e) The interior of the animal cargo space shall be kept clean.

(f) Live guinea pigs and hamsters shall not be transported with any material, substance (e.g., dry ice) or device which may reasonably be expected to be injurious to the health and well-being of the guinea pigs and hamsters unless proper precaution is taken to prevent such injury.

§ 3.38 Food and water requirements.

(a) If live guinea pigs or hamsters are to be transported for a period of more than 6 hours, the animals shall have access to food and water or a type of food, which provides the requirements for food and water in quantity and quality sufficient to satisfy their food and water needs, during transit.

(b) Any dealer, research facility, exhibitor or operator of an auction sale offering any live guinea pig or hamster to any carrier or intermediate handler for transportation, in commerce, shall provide an adequate supply of food or type of food, which provides the requirements for food and water, within the primary enclosure to meet the requirements of this section.

(c) No carrier or intermediate handler shall accept for transportation, in commerce, any live guinea pig or hamster without an adequate supply of food or type of food, which provides the requirements for food and water, within the primary enclosure to meet the requirements of this section.

§ 3.39 Care in transit.

(a) During surface transportation, it shall be the responsibility of the driver or other employee to visually observe the live guinea pigs or hamsters as frequently as circumstances may dictate, but not less than once every 4 hours, to assure that they are receiving sufficient air for normal breathing, their ambient temperatures are within the prescribed limits, all other applicable standards are being complied with and to determine whether any of the live guinea pigs or hamsters are in obvious physical distress and to provide any needed veterinary care as soon as possible. When transported by air, live guinea pigs and hamsters shall be visually observed by the carrier as frequently as circumstances may dictate, but not less than once every 4 hours, if the animal cargo space is accessible during flight. If the animal cargo space is not accessible during flight, the carrier shall visually observe the live guinea pigs or hamsters whenever loaded and unloaded and whenever the animal cargo space is otherwise accessible to assure that they are receiving sufficient air for normal breathing, their ambient temperatures are within the prescribed limits, all other applicable standards are being complied with and to determine whether any such live guinea pigs or hamsters are in obvious physical distress. The carrier shall provide any needed veterinary care as soon as possible. No guinea pig or hamster in obvious physical distress shall be transported in commerce.

(b) During the course of transportation, in commerce, live guinea pigs or hamsters shall not be removed from their primary enclosures unless placed in other primary enclosures or facilities conforming to the requirements provided in this subpart.

§ 3.40 Terminal facilities.

Carriers and intermediate handlers shall not commingle live animal shipments with inanimate cargo. All animal holding areas of a terminal facility of any carrier or intermediate handler wherein live animal shipments are maintained shall be cleaned and sanitized in a manner prescribed in § 3.31 of the standards often enough to prevent an accumulation of debris or excreta, to minimize vermin infestation and to prevent a disease hazard. An effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained for all animal holding areas. Any animal holding area containing live guinea pigs or hamsters shall be provided with fresh air by means of windows, doors, vents, or air conditioning and may be ventilated or air circulated by means of fans, blowers, or an air conditioning system so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans and vents or fans or blowers or air conditioning shall be used for any animal holding area containing live guinea pigs and hamsters when the air temperature within such animal holding area is 23.9° C. (75.° F.) or higher. The air temperature around any live guinea pig or hamster in any animal holding area shall not be allowed to fall below 7.2° C. (45° F.) nor be allowed to exceed 29.5° C. (85° F.) at any time. To ascertain compliance with the provisions of this paragraph, the air temperature around any live guinea pig or hamster shall be measured and read outside the primary enclosure which contains such guinea pig or hamster at a distance not to exceed .91 meters (3 feet) from any one of the external walls of the primary enclosure and measured on a level parallel to the bottom of such primary enclosure at a point which approximates half the distance between the top and bottom of such primary enclosure.

[43 FR 56215, Dec. 1, 1978]

§ 3.41 Handling.

(a) Carriers and intermediate handlers shall move live guinea pigs and hamsters from the animal holding area of the terminal facility to the primary conveyance and from the primary conveyance to the animal holding area of the terminal facility as expeditiously as possible. Carriers and intermediate handlers holding any live guinea pig or hamster in an animal holding area of a terminal facility or in transporting any live guinea pig or hamster from the animal holding area of the terminal facility to the primary conveyance and from the primary conveyance to the animal holding area of the terminal facility, including loading and unloading procedures, shall provide the following:

(1) *Shelter from sunlight.* When sunlight is likely to cause overheating or discomfort, sufficient shade shall be provided to protect the live guinea pigs and hamsters from the direct rays of the sun and such live guinea pigs or hamsters shall not be subjected to surrounding air temperatures which exceed 29.5° C. (85° F.), and which shall be measured and read in the manner prescribed § 3.40 of this part, for a period of more than 45 minutes.

(2) *Shelter from rain or snow.* Live guinea pigs and hamsters shall be provided protection to allow them to remain dry during rain or snow.

(3) *Shelter from cold weather.* Transporting devices shall be covered to provide protection for live guinea pigs and hamsters when the outdoor air temperature falls below 10° C. (50° F.), and such live guinea pigs and hamsters shall not be subjected to surrounding air temperatures which fall below 7.2° C. (45° F.), and which shall be measured and read in the manner prescribed in § 3.40 of this part, for a period of more than 45 minutes.

(b) Care shall be exercised to avoid handling of the primary enclosure in such a manner that may cause physical or emotional trauma to the live guinea pig or hamster contained therein.

(c) Primary enclosures used to transport any live guinea pig or hamster shall not be tossed, dropped, or needlessly tilted and shall not be stacked in a manner which may reasonably be expected to result in their falling.

[43 FR 21163, May 16, 1978, as amended at 43 FR 56216, Dec. 1, 1978]

Subpart C—Specifications for the Humane Handling, Care, Treatment and Transportation of Rabbits

FACILITIES AND OPERATING STANDARDS

§ 3.50 Facilities, general.

(a) *Structural strength.* Indoor and outdoor housing facilities for rabbits shall be structurally sound and shall be maintained in good repair, to protect the animals from injury, to contain the animals, and to restrict the entrance of other animals.

(b) *Water and electric power.* Reliable and adequate electric power, if required to comply with other provisions of this subpart, and adequate potable water shall be available.

(c) *Storage.* Supplies of food and bedding shall be stored in facilities which adequately protect such supplies against infestation or contamination by vermin. Refrigeration shall be provided for supplies of perishable food.

(d) *Waste disposal.* Provision shall be made for the removal and disposal of animal and food wastes, bedding, dead animals, and debris. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, and disease hazards.

(e) *Washroom and sinks.* Facilities, such as washrooms, basins, or sinks, shall be provided to maintain cleanliness among animal caretakers.

[32 FR 3273, Feb. 24, 1967, as amended at 44 FR 63492, Nov. 2, 1979]

§ 3.51 Facilities, indoor.

(a) *Heating.* Indoor housing facilities for rabbits need not be heated.

(b) *Ventilation.* Indoor housing facilities for rabbits shall be adequately ventilated to provide for the health and comfort of the animals at all times. Such facilities shall be provided with fresh air either by means of windows, doors, vents, or air conditioning and shall be ventilated so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans and vents or air conditioning, shall be provided when the ambient temperature is 85° F. or higher.

(c) *Lighting.* Indoor housing facilities for rabbits shall have ample light, by natural or artificial means, or both, of good quality and well distributed. Such lighting shall provide uniformly distributed illumination of sufficient light intensity to permit routine inspection and cleaning during the entire working period. Primary enclosures shall be so placed as to protect the rabbits from excessive illumination.

(d) *Interior surfaces.* The interior building surfaces of indoor housing facilities shall be constructed and maintained so that they are substantially impervious to moisture and may be readily sanitized.

§ 3.52 Facilities, outdoor.

(a) *Shelter from sunlight.* When sunlight is likely to cause overheating or discomfort, sufficient shade shall be provided to allow all rabbits kept outdoors to protect themselves from the direct rays of the sun. When the atmospheric temperature exceeds 90° F. artificial cooling shall be provided by a sprinkler system or other means.

(b) *Shelter from rain or snow.* Rabbits kept outdoors shall be provided with access to shelter to allow them to remain dry during rain or snow.

(c) *Shelter from cold weather.* Shelter shall be provided for all rabbits kept outdoors when the atmospheric temperature falls below 40° F.

(d) *Protection from predators.* Outdoor housing facilities for rabbits shall be fenced or otherwise enclosed to minimize the entrance of predators.

(e) *Drainage.* A suitable method shall be provided to rapidly eliminate excess water.

§ 3.53 Primary enclosures.

All primary enclosures for rabbits shall conform to the following requirements:

(a) *General.* (1) Primary enclosures shall be structurally sound and maintained in good repair to protect the rabbits from injury, to contain them, and to keep predators out.

(2) Primary enclosures shall be constructed and maintained so as to enable the rabbits to remain dry and clean.

(3) Primary enclosures shall be constructed and maintained so that the rabbits contained therein have convenient access to clean food and water as required in this subpart.

(4) The floors of the primary enclosures shall be constructed so as to protect the rabbits' feet and legs from injury. Litter shall be provided in all primary enclosures having solid floors.

(5) A suitable nest box containing clean nesting material shall be provided in each primary enclosure housing a female with a litter less than one month of age.

(b) *Space requirements.* Primary enclosures shall be constructed and maintained so as to provide sufficient space for the animal to make normal postural adjustments with adequate freedom of movement. Each rabbit housed in a primary enclosure shall be provided a minimum amount of floor space, exclusive of the space taken up by food and water receptacles, in accordance with the following table:

Category	Individual weights (pounds)	Minimum space per rabbit (square inches)
Groups	3 through 5	144
	6 through 8	288
	9 or more	432
Individual adults	3 through 5	180
	6 through 8	360
	9 through 11	540
	12 or more	720
Nursing females	3 through 5	576
	6 through 8	720
	9 through 11	864
	12 or more	1080

ANIMAL HEALTH AND HUSBANDRY STANDARDS

§ 3.54 Feeding.

(a) Rabbits shall be fed at least once each day except as otherwise might be required to provide adequate veterinary care. The food shall be free from contamination, wholesome, palatable and of sufficient quantity and nutritive value to meet the normal daily requirements for the condition and size of the rabbit.

(b) Food receptacles shall be accessible to all rabbits in a primary enclosure and shall be located so as to minimize contamination by excreta. All food receptacles shall be kept clean and sanitized at least once every 2 weeks. If self feeders are used for the feeding of dry feed, measures must be taken to prevent molding, deterioration or caking of the feed.

§ 3.55 Watering.

Sufficient potable water shall be provided daily except as might otherwise be required to provide adequate veterinary care. All watering receptacles shall be sanitized when dirty: *Provided, however,* That such receptacles shall be sanitized at least once every 2 weeks.

§ 3.56 Sanitation.

(a) *Cleaning of primary enclosures.* (1) Primary enclosures shall be kept reasonably free of excreta, hair, cobwebs and other debris by periodic cleaning. Measures shall be taken to prevent the wetting of rabbits in such enclosures if a washing process is used.

(2) In primary enclosures equipped with solid floors, soiled litter shall be removed and replaced with clean litter at least once each week.

(3) If primary enclosures are equipped with wire or mesh floors, the troughs or pans under such enclosures

shall be cleaned at least once each week. If worm bins are used under such enclosures they shall be maintained in a sanitary condition.

(b) *Sanitization of primary enclosures.* (1) Primary enclosures for rabbits shall be sanitized at least once every 30 days in the manner provided in paragraph (b)(3) of this section.

(2) Prior to the introduction of rabbits into empty primary enclosures previously occupied, such enclosures shall be sanitized in the manner provided in paragraph (b)(3) of this section.

(3) Primary enclosures for rabbits shall be sanitized by washing them with hot water (180° F.) and soap or detergent as in a mechanical cage washer, or by washing all soiled surfaces with a detergent solution followed by a safe and effective disinfectant, or by cleaning all soiled surfaces with live steam or flame.

(c) *Housekeeping.* Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart. Premises shall remain free of accumulations of trash.

(d) *Pest control.* An effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained.

§ 3.57 Employees.

A sufficient number of employees shall be utilized to maintain the prescribed level of husbandry practices set forth in this subpart. Such practices shall be under the supervision of an animal caretaker who has a background in animal husbandry or care.

§ 3.58 Classification and separation.

Animals housed in the same primary enclosure shall be maintained in compatible groups, with the following additional restrictions:

(a) Rabbits shall not be housed in the same primary enclosure with any other species of animals unless required for scientific reasons.

(b) Rabbits under quarantine or treatment for a communicable disease shall be separated from other rabbits and other susceptible species of animals in such a manner as to minimize dissemination of such disease.

§ 3.59 Veterinary care.

(a) Programs of disease control and prevention, euthanasia, and adequate veterinary care shall be established and maintained under the supervision and assistance of a doctor of veterinary medicine.

(b) Each rabbit shall be observed at least every 48 hours by the animal caretaker in charge, or by someone working under his direct supervision, for evidence of disease or injury. Sick or diseased, injured, lame or blind rabbits shall be provided with veterinary care or humanely disposed of unless such action is inconsistent with the research purposes for which such animal was obtained and is being held.

(c)(1) In the case of a research facility, the program of adequate veterinary care shall include the appropriate use of anesthetic, analgesic, or tranquilizing drugs, when such use would be proper in the opinion of the attending veterinarian at the research facility. The use of these three classes of drugs shall be in accordance with the currently accepted veterinary medical practice as cited in appropriate professional journals or reference guides which shall produce in the individual subject animal a high level of tranquilization, anesthesia, or analgesia consistent with the protocol or design of the experiment.

(2) It shall be incumbent upon each research facility through its animal care committee and/or attending veterinarian to provide guidelines and consultation to research personnel with respect to the type and amount of tranquilizers, anesthetics, or analgesics recommended as being appropriate for each species of animal used by that institution.

(3) The use of these three classes of drugs shall effectively minimize the pain and discomfort of the animals while under experimentation.

[32 FR 3273, Feb. 24, 1967, as amended at 36 FR 24925, Dec. 24, 1971]

TRANSPORTATION STANDARDS

AUTHORITY: Sections 3.60 through 3.66 issued under secs. 3, 5, 6, 10, 11, 14, 16, 17, 21; 80 Stat. 353; 84 Stat. 1561, 1562, 1563, 1564; 90 Stat. 418, 420, 423 (7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2144, 2146, 2147, 2151); 37 FR 28464, 28477, 38 FR 19141.

SOURCE: Sections 3.60 through 3.66 appear at 42 FR 31565, June 21, 1977, unless otherwise noted.

§ 3.60 Consignments to carriers and intermediate handlers.

(a) Carriers and intermediate handlers shall not accept any live rabbit presented by any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or any State or local government for shipment, in commerce, more than 4 hours prior to the scheduled departure of the primary conveyance on which it is to be transported: *Provided, however,* That the carrier or intermediate handler and any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or any State or local government may mutually agree to extend the time of acceptance to not more than 6 hours if specific prior scheduling of the animal shipment to destination has been made.

(b) Any carrier or intermediate handler shall only accept for transportation or transport, in commerce, any live rabbit in a primary enclosure which conforms to the requirements set forth in § 3.61 of the standards: *Provided, however,* That any carrier or intermediate handler may accept for transportation or transport, in commerce, any live rabbit consigned by any department, agency, or instrumentality of the United States having laboratory animal facilities or exhibiting animals or any licensed or registered dealer, research facility, exhibitor, or operator of any auction sale, if such consignor furnishes to the carrier or intermediate handler a certificate, signed by the consignor, stating that the primary enclosure complies with § 3.61 of the standards, unless such primary enclosure is obviously defective or damaged and it is apparent that it cannot reasonably be expected to contain the live rabbit without causing suffering or injury to such live rabbit. A copy of such certificate shall accompany the shipment to destination. The certificate shall include at least the following information:

(1) Name and address of the consignor;

(2) The number of rabbits in the primary enclosure(s);

(3) A certifying statement (e.g., "I hereby certify that the —— (number) primary enclosure(s) which are used to transport the animal(s) in this shipment complies (comply) with USDA standards for primary enclosures (9 CFR Part 3)."); and

(4) The signature of the consignor, and date.

(c) Carriers or intermediate handlers whose facilities fail to meet the minimum temperature allowed by the standards may accept for transportation or transport, in commerce, any live rabbit consigned by any department, agency, or instrumentality of the United States or of any State or local government, or by any person (including any licensee or registrant under the Act, as well as any private individual) if the consignor furnishes to the carrier or intermediate handler a certificate executed by a veterinarian accredited by this Department pursuant to Part 160 of this title on a specified date which shall not be more than 10 days prior to delivery of such rabbit for transportation in commerce, stating that such live rabbit is acclimated to air temperatures lower than those prescribed in §§ 3.65 and 3.66. A copy of such certificate shall accompany the shipment to destination. The certificate shall include at least the following information:

(1) Name and address of the consignor;

(2) The number of rabbits in the shipment;

(3) A certifying statement (e.g., "I hereby certify that the animal(s) in this shipment is (are), to the best of my knowledge, acclimated to air temperatures lower than 7.2° C. (45° F.)."; and

(4) The signature of the USDA accredited veterinarian, assigned accreditation number, and date.

(d) Carriers and intermediate handlers shall attempt to notify the consignee at least once in every 6 hour period following the arrival of any live rabbit at the animal holding area of the terminal cargo facility. The time, date, and method of each attempted notification and the final notification to the consignee and the name of the person notifying the consignee shall be recorded on the copy of the shipping document retained by the carrier or intermediate handler and on a copy of the shipping document accompanying the animal shipment.

[42 FR 31565, June 21, 1977, as amended at 43 FR 21164, May 16, 1978; 44 FR 63493, Nov. 2, 1979]

§ 3.61 Primary enclosures used to transport live rabbits.

No dealer, research facility, exhibitor, or operator of an auction sale shall offer for transportation or transport, in commerce, any live rabbit in a primary enclosure which does not conform to the following requirements:

(a) Primary enclosures, such as compartments, transport cages, cartons, or crates, used to transport live rabbits shall be constructed in such a manner that:

(1) The stuctural strength of the enclosure shall be sufficient to contain the live rabbits and to withstand the normal rigors of transportation;

(2) The interior of the enclosure shall be free from any protrusions that could be injurious to the live rabbits contained therein;

(3) The openings of such enclosures are easily accessible at all times for emergency removal of the live rabbits;

(4) Except as provided in paragraph (h) of this section, there are ventilation openings located on two opposite walls of the primary enclosure and the ventilation openings on each such wall shall be at least 16 percent of the total surface area of each such wall, or there are ventilation openings located on all four walls of the primary enclosure and the ventilation openings on each such wall shall be at least 8 percent of the total surface area of each such wall: *Provided, however,* That at least one-third of the total minimum area required for ventilation of the primary enclosure shall be located on the lower one-half of the primary enclosure and at least one-third of the total minimum area required for ventilation of the primary enclosure shall be located on the upper one-half of the primary enclosure;

(5) Except as provided in paragraph (h) of this section, projecting rims or other devices shall be on the exterior of the outside walls with any ventilation openings to prevent obstruction of the ventilation openings and to provide a minimum air circulation space 1.9 centimeters (.75 inch) between the primary enclosure and any adjacent cargo or conveyance wall; and

(6) Except as provided in paragraph (h) of this section, adequate handholds or other devices for lifting shall be provided on the exterior of the primary enclosure to enable the primary enclosure to be lifted without tilting and to ensure that the person handling the primary enclosure will not be in contact with the rabbit.

(b) Live rabbits transported in the same primary enclosure shall be maintained in compatible groups and shall not be transported in the same primary enclosure with other specie of animals.

(c) Primary enclosures used to transport live rabbits shall be large enough to ensure that each rabbit contained therein has sufficient space to turn about freely and to make normal postural adjustments.

(d) Not more than 15 live rabbits shall be transported in the same primary enclosure.

(e) Primary enclosures used to transport live rabbits as provided in this section shall have solid bottoms to prevent leakage in shipment and shall be cleaned and sanitized in a manner prescribed in § 3.56 of the standards, if previously used. Such primary enclosures shall contain clean litter of a suitable absorbent material which is safe and nontoxic to the rabbits, in sufficient quantity to absorb and cover excreta, unless the rabbits are on wire or other nonsolid floors.

(f) Primary enclosures used to transport live rabbits, except where such primary enclosures are permanently affixed in the animal cargo space of the primary conveyance, shall be clearly marked on top and on one or more sides with the works "Live Animal" in letters not less than 2.5 centimeters (1 inch) in height, and with arrows or other markings, to indicate the correct upright position of the container.

(g) Documents accompanying the shipment shall be attached in an easily accessible manner to the outside of a primary enclosure which is part of such shipment.

(h) When a primary enclosure is permanently affixed within the animal cargo space of the primary conveyance so that the front opening is the only source of ventilation for such primary enclosure, the front opening shall open directly to the outside or to an unobstructed aisle or passageway within the primary conveyance. Such front ventilation opening shall be at least 90 percent of the total surface area of the front wall of the primary enclosure and covered with bars, wire mesh or smooth expanded metal.

[42 FR 31565, June 21, 1977, as amended at 43 FR 21164, May 16, 1978]

§ 3.62 Primary conveyances (motor vehicle, rail, air, and marine).

(a) The animal cargo space of primary conveyances used in transporting live rabbits shall be designed and constructed to protect the health, and ensure the safety and comfort of the rabbits contained therein at all times.

(b) The animal cargo space shall be constructed and maintained in a manner to prevent the ingress of engine exhaust fumes and gases from the primary conveyance during transportation in commerce.

(c) No live rabbit shall be placed in an animal cargo space that does not have a supply of air sufficient for normal breathing for each live animal contained therein, and the primary enclosures shall be positioned in the animal cargo space in such a manner that each rabbit has access to sufficient air for normal breathing.

(d) Primary enclosures shall be positioned in the primary conveyance in such a manner that in an emergency the live rabbits can be removed from the primary conveyance as soon as possible.

(e) The interior of the animal cargo space shall be kept clean.

(f) Live rabbits shall not be transported with any material, substance (e.g., dry ice) or device which may reasonably be expected to be injurious to the health and well-being of the rabbits unless proper precaution is taken to prevent such injury.

§ 3.63 Food and water requirements.

(a) If live rabbits are to be transported for a period of more than 6 hours, they shall have access to food and water or a type of food, which provides the requirements for food and water in quantity and quality sufficient to satisfy their food and water needs, during transit.

(b) Any dealer, research facility, exhibitor or operator of an auction sale offering any live rabbit to any carrier or intermediate handler for transportation, in commerce, shall provide an adequate supply of food or type of food, which provides the requirements for food and water, within the primary enclosure to meet the requirements of this section.

(c) No carrier or intermediate handler shall accept for transportation, in commerce, any live rabbit without an adequate supply of food or type of food, which provides the requirements for food and water, within the primary enclosure to meet the requirements of this section.

§ 3.64 Care in transit.

(a) During surface transportation, it shall be th responsibility of the driver or other employee to visually observe the live rabbits as frequently as circumstances may dictate, but not less than once every 4 hours, to assure that they are receiving sufficient air for normal breathing, their ambient temperatures are within the prescribed limits, all other applicable standards are being complied with and to determine whether any of the live rabbits are in obvious physical disress and to provide any needed veterinary care as soon as possible. When transported by air, live rabbits shall be visually observed by the carrier as frequently as circumstances may dictate, but not less than once every 4 hours, if the cargo space is accessible during flight. If the animal cargo space is not accessible during flight, the carrier shall visually observe the live rabbits whenever loaded and unloaded and whenever the animal cargo space is otherwise accessible to assure that they are receiving sufficient air for normal breathing, their ambient temperatures are within the prescribed limits, all other applicable standards are being complied with and to determine whether any such live rabbits are in obvious physical distress. The carrier shall provide any needed veterinary care as soon as possible. No rabbit in obvious physical distress shall be transported in commerce.

(b) During the course of transportation, in commerce, live rabbits shall not be removed from their primary enclosures unless placed in other primary enclosures or facilities conforming to the requirements provided in this subpart.

§ 3.65 Terminal facilities.

Carriers and intermediate handlers shall not commingle live animal shipments with inanimate cargo. All animal holding areas of a terminal facility of any carrier or intermediate handler wherein live animal shipments are maintained shall be cleaned and sanitized in a manner prescribed in § 3.56 of the standards often enough to prevent an accumulation of debris or excreta, to minimize vermin infestation and to prevent a disease hazard. An effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained for all animal holding areas. Any animal holding area containing live rabbits shall be provided with fresh air by means of windows, doors, vents, or air conditioning and may be ventilated or air circulated by means of fans, blowers, or an air conditioning system so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans and vents or fans or blowers or air conditioning shall be used for any animal holding area containing live rabbits when the air temperature within such animal holding area is 23.9° C. (75° F.) or higher. The air temperature around any live rabbit in any animal holding area shall not be allowed to fall below 7.2° C. (45° F.) nor be allowed to exceed 29.5° C. (85° F.) at any time. To ascertain compliance with the provisions of this paragraph, the air temperature around any live rabbit shall be measured and read outside the primary enclosure which contains such rabbit at a distance not to exceed .91 meters (3 feet) from any one of the external walls of the primary enclosure and on a level parallel to the bottom of such primary enclosure at a point which approximates half the distance between the top and bottom of such primary enclosure.

[43 FR 56216, Dec. 1, 1978]

§ 3.66 Handling.

(a) Carriers and intermediate handlers shall move live rabbits from the animal holding area of the terminal facility to the primary conveyance and from the primary conveyance to the animal holding area of the terminal facility as expeditiously as possible. Carriers and intermediate handlers holding any live rabbit in an animal holding area of a terminal facility or in transporting any live rabbit from the animal holding area of the terminal facility to the primary conveyance and from the primary conveyance to the animal holding area of the terminal facility, including loading and unloading procedures, shall provide the following:

(1) *Shelter from sunlight.* When sunlight is likely to cause overheating or discomfort, sufficient shade shall be provided to protect the live rabbits from the direct rays of the sun and such live rabbits shall not be subjected to surrounding air temperatures which exceed 29.5° C. (85° F.), and which shall be measured and read in the manner prescribed in § 3.65 of this part, for a period of more than 45 minutes.

(2) *Shelter from rain or snow.* Live rabbits shall be provided protection to allow them to remain dry during rain or snow.

(3) *Shelter from cold weather.* Transporting devices shall be covered to provide protection for live rabbits when the outdoor air temperature falls below 10° C. (50° F.), and such live rabbits shall not be subjected to surrounding air temperatures which fall

below 7.2° C. (45° F.), and which shall be measured and read in the manner prescribed in § 3.65 of this part, for a period of more than 45 minutes unless such rabbits are accompanied by a certificate of acclimation to lower temperatures as prescribed in § 3.60(c).

(b) Care shall be exercised to avoid handling of the primary enclosure in such a manner that may cause physical or emotional trauma to the live rabbit contained therein.

(c) Primary enclosures used to transport any live rabbit shall not be tossed, dropped, or needlessly tilted and shall not be stacked in a manner which may reasonably be expected to result in their falling.

[43 FR 21164, May 16, 1978, as amended at 43 FR 56216, Dec. 1, 1978]

Subpart D—Specifications for the Humane Handling, Care, Treatment, and Transportation of Nonhuman Primates[2]

FACILITIES AND OPERATING STANDARDS

§ 3.75 Facilities, general.

(a) *Structural strength.* The indoor and outdoor housing facilities for nonhuman primates shall be structurally sound and shall be maintained in good repair, to protect the animals from injury, to contain the animals, and to restrict the entrance of other animals.

(b) *Water and electric power.* Reliable and adequate electric power, if required to comply with other provisions of this subpart, and adequate potable water shall be available.

(c) *Storage.* Supplies of food and bedding shall be stored in facilities which adequately protect such supplies against infestation or contamination by vermin. Refrigeration shall be provided for supplies of perishable food.

(d) *Waste disposal.* Provision shall be made for the removal and disposal of animal and food wastes, bedding, dead animals, and debris. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, and disease hazards.

(e) *Washroom and sinks.* Facilities, such as washrooms, basins, or sinks, shall be provided to maintain cleanliness among animal caretakers.

[32 FR 3273, Feb. 24, 1967, as amended at 44 FR 63492, Nov. 2, 1979]

§ 3.76 Facilities, indoor.

(a) *Heating.* Indoor housing facilities for nonhuman primates shall be sufficiently heated when necessary to protect the animals from the cold, and to provide for their health and comfort. The ambient temperature shall not be allowed to fall below 50° F.

(b) *Ventilations.* Indoor housing facilities for nonhuman primates shall be adequately ventilated to provide for the health and comfort of the animals at all times. Such facilities shall be provided with fresh air either by means of windows, doors, vents, or air conditioning and shall be ventilated so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans and vents or air conditioning, shall be provided when the ambient temperature is 85° F. or higher.

(c) *Lighting.* Indoor housing facilities for nonhuman primates shall have ample light, by natural or artificial means, or both, of good quality and well distributed. Such lighting shall provide uniformly distributed illumination of sufficient light intensity to permit routine inspection and cleaning during the entire working period. Primary enclosures shall be so placed as to protect the nonhuman primates from excessive illumination.

(d) *Interior surfaces.* The interior building surfaces of indoor housing facilities shall be constructed and maintained so that they are substantially impervious to moisture and may be readily sanitized.

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[2] Nonhuman primates include a great diversity of forms, ranging from the marmoset weighing only a few ounces, to the adult gorilla weighing hundreds of pounds. They come from Asia, Africa, and Central and South America, and they live in different habitats. Their nutritional and activity requirements differ as do their social and environmental requirements. As a result, the conditions appropriate for one species do not necessarily apply to another; therefore, discretion must be used in interpreting these standards.

(e) *Drainage.* A suitable method shall be provided to rapidly eliminate excess water from indoor housing facilities. If drains are used, they shall be properly constructed and kept in good repair to avoid foul odors therefrom. If closed drainage systems are used, they shall be equipped with traps and so installed as to prevent any backup of sewage onto the floor of the room.

§ 3.77 Facilities, outdoor.

(a) *Shelter from sunlight.* When sunlight is likely to cause overheating or discomfort, sufficient shade shall be provided to allow all nonhuman primates kept outdoors to protect themselves from the direct rays of the sun.

(b) *Shelter from rain or snow.* Nonhuman primates kept outdoors shall be provided with access to shelter to allow them to remain dry during rain or snow.

(c) *Shelter from cold weather.* Shelter shall be provided for all nonhuman primates kept outdoors to afford comfort and protection to such animals appropriate for the local climatic conditions and the nonhuman primate species concerned.

(d) *Drainage.* A suitable method shall be provided to rapidly eliminate excess water.

§ 3.78 Primary enclosures.

All primary enclosures for nonhuman primates shall conform to the following requirements:

(a) *General.* (1) Primary enclosures shall be structurally sound and maintained in good repair to protect the nonhuman primates from injury, to contain them, and to keep predators out.

(2) Primary enclosures shall be constructed and maintained so as to enable the nonhuman primates to remain dry and clean.

(3) Primary enclosures shall be constructed and maintained so that the nonhuman primates contained therein have convenient access to clean food and water as required in this subpart.

(4) The floors of the primary enclosures shall be constructed so as to protect the nonhuman primates from injury.

(b) *Space requirements.* (1) Prima enclosures shall be constructed a maintained so as to provide sufficie space to allow each nonhuman p mate to make normal postural adju ments with adequate freedom of mov ment.

(2) Each nonhuman primate hous in a primary enclosure shall be prov ed with a minimum floor space equ to an area of at least three times t area occupied by such primate wh standing on four feet.

ANIMAL HEALTH AND HUSBANDRY STANDARDS

§ 3.79 Feeding.

(a) Nonhuman primates shall be at least once each day except as oth wise might be required to provide a quate veterinary care. The food sh be free from contamination, who some, palatable, and of suffici quantity and nutritive value to m the normal daily requirements for t condition and size of the nonhum primate.

(b) Food, and food receptacles used, shall be accessible to all non man primates and shall be placed so to minimize contamination by excre Food receptacles shall be kept cl and shall be sanitized at least o every 2 weeks. If self feeders are us measures shall be taken to prev molding, deterioration or caking food.

§ 3.80 Watering.

If potable water is not accessible the nonhuman primates at all tim such water shall be offered to them least twice daily except as might o erwise be required to provide adequ veterinary care. All watering recep cles shall be kept clean and all such ceptacles shall be sanitized at le once every 2 weeks.

§ 3.81 Sanitation.

(a) *Cleaning of primary enclosu* Excreta shall be removed from mary enclosures as often as necess to prevent contamination of the n human primates contained ther and to reduce disease hazards odors. When hosing or flushing me ods are used for this purpose, measures shall be taken to prevent animals confined in such enclosures from being wetted involuntarily.

(b) *Sanitization of enclosures.* (1) Prior to the introduction of nonhuman primates into primary enclosures previously occupied by other nonhuman primates, such enclosures shall be sanitized in the manner provided in paragraph (b)(3) of this section.

(2) Primary enclosures for nonhuman primates shall be sanitized often enough to prevent an accumulation of debris or excreta, or a disease hazard: *Provided, however,* That such enclosures shall be sanitized at least once every 2 weeks in the manner provided in paragraph (b)(3) of this section.

(3) Cages, rooms and hard surfaced pens or runs shall be sanitized either by washing them with hot water (180° F.) and soap or detergent, as in a mechanical cage washer, or by washing all soiled surfaces with a detergent solution followed by a safe and effective disinfectant, or by cleaning all soiled surfaces with live steam. Pens or runs using gravel, sand, or dirt, shall be sanitized by removing the soiled gravel, sand, or dirt and replacing it as necessary.

(c) *Housekeeping.* Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed hubandry practices set forth in this subpart. Premises shall remain free of accumulations of trash.

(d) *Pest control.* An effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained.

§ 3.82 Employees.

A sufficient number of employees shall be utilized to maintain the prescribed level of husbandry practices set forth in this subpart. Such practices shall be under the supervision of an animal caretaker who has a background in animal husbandry or care.

§ 3.83 Classification and separation.

Nonhuman primates housed in the same primary enclosure shall be maintained in compatible groups and shall not be housed in the same primary enclosure with animal species other than nonhuman primates.

§ 3.84 Veterinary care.

(a) Programs of disease control and prevention, euthanasia, and adequate veterinary care shall be established and maintained under the supervision and assistance of a doctor of veterinary medicine.

(b) Each nonhuman primate shall be observed daily by the animal caretaker in charge or by someone working under his direct supervision. Sick or diseased, injured, lame, or blind nonhuman primates shall be provided with veterinary care or humanely disposed of unless such action is inconsistent with the research purposes for which the animal was obtained and is being held.

(c)(1) In the case of a research facility, the program of adequate veterinary care shall include the appropriate use of anesthetic, analgesic, or tranquilizing drugs, when such use would be proper in the opinion of the attending veterinarian at the research facility. The use of these three classes of drugs shall be in accordance with the currently accepted veterinary medical practice as cited in appropriate professional journals or reference guides which shall produce in the individual subject animal a high level of tranquilization, anesthesia, or analgesia consistent with the protocol or design of the experiment.

(2) It shall be incumbent upon each research facility through its animal care committee and/or attending veterinarian to provide guidelines and consultation to research personnel with respect to the type and amount of tranquilizers, anesthetics, or analgesics recommended as being appropriate for each species or animal used by that institution.

(3) The use of these three classes of drugs shall effectively minimize the pain and discomfort of the animals while under experimentation.

[32 FR 3273, Feb. 24, 1967, as amended at 36 FR 24925, Dec. 24, 1971]

TRANSPORTATION STANDARDS

AUTHORITY: Sections 3.85 through 3.91 issued under secs. 3, 5, 6, 10, 11, 14, 16, 17, 21; 80 Stat. 353; 84 Stat. 1561, 1562, 1563, 1564; 90 Stat. 418, 419, 420, 423 (7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2144, 2146, 2147, 2151); 37 FR 28464, 28477, 38 FR 19141.

SOURCE: Sections 3.85 through 3.91 appear at 42 FR 31567, June 21, 1977, unless otherwise noted.

§ 3.85 Consignments to carriers and intermediate handlers.

(a) Carriers and intermediate handlers shall not accept any live nonhuman primate presented by any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or any State or local government for shipment, in commerce, more than 4 hours prior to the scheduled departure of the primary conveyance on which it is to be transported: *Provided, however,* That the carrier or intermediate handler and any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or any State or local government may mutually agree to extend the time of acceptance to not more than 6 hours if specific prior scheduling of the animal shipment to destination has been made.

(b) Any carrier or intermediate handler shall only accept for transportation or transport, in commerce, any live nonhuman primate in a primary enclosure which conforms to the requirements set forth in § 3.86 of the standards: *Provided, however,* That any carrier or intermediate handler may accept for transportation or transport, in commerce, any live nonhuman primate consigned by any department, agency, or instrumentality of the United States having laboratory animal facilities or exhibiting animals or any licensed or registered dealer, research facility, exhibitor, or operator of an auction sale if the consignor furnishes to the carrier or intermediate handler a certificate, signed by the consignor, stating that the primary enclosure complies with § 3.86 of the standards, unless such primary enclosure is obviously defective or damaged and it is apparent that it cannot reasonably be expected to contain the live nonhuman primate without causing suffering or injury to such live nonhuman primate. A copy of such certificate shall accompany the shipment to destination. The certificate shall include at least the following information:

(1) Name and address of the consignor;

(2) The number of nonhuman primates in the primary enclosure(s);

(3) A certifying statement (e.g., "I hereby certify that the —— (number) primary enclosure(s) which are used to transport the animal(s) in this shipment complies (comply) with USDA standards for primary enclosures (9 CFR Part 3)."); and

(4) The signature of the consignor, and date.

(c) Carriers or intermediate handlers whose facilities fail to meet the minimum temperature allowed by the standards may accept for transportation or transport, in commerce, any live nonhuman primate consigned by any department, agency, or instrumentality of the United States or of any State or local government, or by any person (including any licensee or registrant under the Act, as well as any private individual) if the consignor furnishes to the carrier or intermediate handler a certificate executed by a veterinarian accredited by this Department pursuant to Part 160 of this title on a specified date which shall not be more than 10 days prior to delivery of such nonhuman primate for transportation in commerce, stating that such live nonhuman primates is acclimated to air temperatures lower than those prescribed in §§ 3.90 and 3.91. A copy of such certificate shall accompany the shipment to destination. The certificate shall include the following information:

(1) Name and address of the consignor;

(2) The number of nonhuman primates in the shipment;

(3) A certifying statement (e.g., "I hereby certify that the animal(s) in this shipment is (are), to the best of my knowledge, acclimated to air temperatures lower than 7.2° C. (45° F.)"); and

(4) The signature of the USDA accredited veterinarian, assigned accreditation number, and date.

(d) Carriers and intermediate handlers shall attempt to notify the consignee at least once in every 6 hour period following the arrival of any live nonhuman primate at the animal holding area of the terminal cargo facility. The time, date, and method of each attempted notification and the final notification to the consignee and the name of the person notifying the consignee shall be recorded on the copy of the shipping document retained by the carrier or intermediate handler and on a copy of the shipping document accompanying the animal shipment.

[42 FR 31567, June 21, 1977, as amended at 43 FR 21165, May, 16, 1978; 44 FR 63493, Nov. 2, 1979]

§ 3.86 Primary enclosures used to transport live nonhuman primates.

No dealer, research facility, exhibitor, or operator of an auction sale shall offer for transportation or transport, in commerce, any live nonhuman primate in a primary enclosure which does not conform to the following requirements:

(a) Primary enclosures, such as compartments, transport cages, cartons, or crates, used to transport live nonhuman primates shall be constructed in such a manner that (1) the structural strength of the enclosure shall be sufficient to contain the live nonhuman primate and to withstand the normal rigors of transportation; (2) the interior of the enclosure shall be free from any protrusions that could be injurious to the live nonhuman primate contained therein; (3) no part of the live nonhuman primate will be exposed outside of the primary enclosure which may cause injury to the animal or to persons who are nearby or who handle the primary enclosure; (4) the openings of such enclosures are easily accessible at all times for emergency removal of the live nonhuman primates; (5) the openings which provide access into the primary enclosure shall be secured with locking devices capable of preventing accidental openings; (6) except as provided in paragraph (a)(4) of this section, there are ventilation openings located on two opposite walls of the primary enclosure and the ventilation openings on each such wall shall be at least 16 percent of the total surface area of each such wall, or there are ventilation openings located on all four walls of the primary enclosure and the ventilation openings on each such wall shall be at least 8 percent of the total surface area of each such wall: *Provided, however,* That at least one-third of the total minimum area required for ventilation of the primary enclosure shall be located on the lower one-half of the primary enclosure and at least one-third of the total minimum area required for ventilation of the primary enclosure shall be located on the upper one-half of the primary enclosure; (7) except as provided in paragraph (h) of this section, projecting rims or other devices shall be on the exterior of the outside walls with any ventilation openings to prevent obstruction of the ventilation openings and to provide a minimum air circulation space of 1.9 centimeters (.75 inches) between the primary enclosure and any adjacent cargo or conveyance wall; and (8) except as provided in paragraph (h) of this section, adequate handholds or other devices for lifting shall be provided on the exterior of the primary enclosure to enable the primary enclosure to be lifted without tilting and to ensure that the person handling the primary enclosure will not be in contact with the nonhuman primate.

(b) Live nonhuman primates transported in the same primary enclosure shall be of the same species and maintained in compatible groups. Nonhuman primates which have not reached puberty shall not be transported in the same primary enclosures with adult nonhuman primates other than their dams. Any female nonhuman primate in season (estrus) shall not be transported in the same primary enclosure with any male nonhuman primate.

(c) Primary enclosures used to transport live nonhuman primates shall be large enough to ensure that each animal contained therin has sufficient space to turn about freely in a stance whereby both feet and hands are on the floor and can sit in an upright position: *Provided, however*, That certain larger species may be restricted in their movements according to professionally acceptable standards when such freedom of movement would constitute a danger to the live nonhuman primates, their handlers, or other persons.

(d) No more than ten live nonhuman primates shall be transported in a primary enclosure.

(e) Primary enclosures used to transport live nonhuman primates as provided in this section shall have solid bottoms to prevent leakage in shipment and shall be cleaned and sanitized in a manner prescribed in § 3.81 of this part, if previously used. Such primary enclosures shall contain clean litter of a suitable absorbent material, which is safe and nontoxic to nonhuman primates, in sufficient quantity to absorb and cover excreta, unless the nonhuman primates are on wire or other nonsolid floors.

(f) Primary enclosures used to transport live nonhuman primates, except where such primary enclosures are permanently affixed in the animal cargo space of the primary conveyance, shall be clearly marked on top and on one or more sides with the words "Wild Animals" in letters not less than 2.5 centimeters (1 inch) in height, and with arrows or other markings, to indicate the correct upright position of the container.

(g) Documents accompanying the shipment shall be attached in an easily accessible manner to the outside of a primary enclosure which is part of such shipment.

(h) When a primary enclosure is permanently affixed within the animal cargo space of the primary conveyance so that the front opening is the only source of ventilation for such primary enclosure, the front opening shall open directly to the outside or to an unobstructed aisle or passageway within the primary conveyance. Such front ventilation opening shall be at least 90 percent of the total surface area of the front wall of the primary enclosure and covered with bars, wire mesh or smooth expanded metal.

[42 FR 31567, June 21, 1977, as amended at 43 FR 21165, May 16, 1978]

§ 3.87 Primary conveyances (motor vehicle, rail, air, and marine).

(a) The animal cargo space of primary conveyances used in transporting live nonhuman primates shall be designed and constructed to protect the health, and ensure the safety and comfort of the nonhuman primates contained therein at all times.

(b) The animal cargo space shall be constructed and maintained in a manner to prevent the ingress of engine exhaust fumes and gases from the primary conveyance during transportation in commerce.

(c) No live nonhuman primate shall be placed in an animal cargo space that does not have a supply of air sufficient for normal breathing for each live animal contained therein, and the primary enclosures shall be positioned in the animal cargo space in such a manner that each nonhuman primate has access to sufficient air for normal breathing.

(d) Primary enclosures shall be positioned in the primary conveyance in such a manner that in an emergency the live nonhuman primates can be removed from the primary conveyance as soon as possible.

(e) The interior of the animal cargo space shall be kept clean.

(f) Live nonhuman primates shall not be transported with any material, substance (e.g., dry ice) or device which may reasonably be expected to be injurious to the health and well-being of the nonhuman primates unless proper precaution is taken to prevent such injury.

§ 3.88 Food and water requirements.

(a) All live nonhuman primates shall be offered potable water within 4 hours prior to being transported in commerce. Dealers, exhibitors, research facilities and operators of auction sales shall provide potable water to all live nonhuman primates transported in their own primary conveyance at least every 12 hours after such transportation is initiated, and carriers and intermediate handlers shall provide potable water to all live nonhuman primates at least every 12 hours after acceptance for transportation in commerce.

(b) Each live adult nonhuman primate over 1 year of age shall be fed at least once in each 24 hour period. Live nonhuman primates less than 1 year of age shall have food made available to them every 12 hours. The time periods provided for in this paragraph shall apply to carriers and intermediate handlers after acceptance of any live nonhuman primates for transportation, in commerce, and shall apply to dealers, exhibitors, research facilities, and operators of auction sales who transport live nonhuman primates in their own primary conveyance after such transportation is initiated.

(c) Any dealer, research facility, exhibitor or operator of an auction sale offering any live nonhuman primate to any carrier or intermediate handler for transportation in commerce shall affix to the outside of the primary enclosure used for transporting such nonhuman primate, written instructions concerning the food and water requirements of such nonhuman primate while being so transported.

(d) No carrier or intermediate handler shall accept any live nonhuman primate for transportation in commerce unless written instructions concerning the food and water requirements of such nonhuman primate while being so transported is affixed to the outside of its primary enclosure.

§ 3.89 Care in transit.

(a) During surface transportation, it shall be the responsibility of the driver or other employee to visually observe the live nonhuman primates as frequently as circumstances may dictate, but not less than once every 4 hours, to assure that they are receiving sufficient air for normal breathing, their ambient temperatures are within the prescribed limits, all other applicable standards are being complied with and to determine whether any of the live nonhuman primates are in obvious physical distress and to provide any needed veterinary care as soon as possible. When transported by air, live nonhuman primates shall be visually observed by the carrier as frequently as circumstances may dictate, but not less than once every 4 hours, if the animal cargo space is accessible during flight. If the animal cargo space is not accessible during flight, the carrier shall visually observe the live nonhuman primates whenever loaded and unloaded and whenever the animal cargo space is otherwise accessible to assure that they are receiving sufficient air for normal breathing, their ambient temperatures are within the prescribed limits, all other applicable standards are being complied with and to determine whether any such live nonhuman primates are in obvious physical distress. The carrier shall provide any needed veterinary care as soon as possible. No nonhuman primate in obvious physical distress shall be transported in commerce.

(b) During the course of transportation, in commerce, live nonhuman primates shall not be removed from their primary enclosures unless placed in other primary enclosures of facilities conforming to the requirements provided in this subpart.

§ 3.90 Terminal facilities

Carriers and intermediate handlers shall not commingle live animal shipments with inanimate cargo. All animal holding areas of a terminal facility of any carrier or intermediate handler wherein live animal shipments are maintained shall be cleaned and sanitized in a manner prescribed in § 3.81 of the standards often enough to prevent an accumulation of debris or excreta, to minimize vermin infestation and to prevent a disease hazard. An effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained for all animal holding areas. Any animal holding area containing live nonhuman primates shall be provided with fresh air by means of windows, doors, vents, or air conditioning and may be ventilated or air circulated by means of fans, blowers, or an air conditioning system so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans and vents or fans or blowers or air conditioning shall be used for any animal holding area containing live nonhuman primates when the air temperature within such animal holding area is 23.9°C. (75.°F.) or higher. The air temperature around any live nonhuman primate in any animal holding area shall not be allowed to fall below 7.2°C. (45°F.) nor be allowed to exceed 29.5°C. (85°F.) at any time: *Provided, however,* That no live nonhuman primate shall be subjected to surrounding air temperatures which exceed 23.9°C. (75°F.) for more than 4 hours at any time. To ascertain compliance with the provisions of this paragraph, the air temperature around any live nonhuman primate shall be measured and read outside the primary enclosure which contains such nonhuman primate at a distance not to exceed .91 meters (3 feet) from any one of the external walls of the primary enclosure and on a level parallel to the bottom of such primary enclosure at a point which approximates half the distance between the top and bottom of such primary enclosure.

[43 FR 56216, Dec. 1, 1978]

§ 3.91 Handling.

(a) Carriers and intermediate handlers shall move live nonhuman primates from the animal holding area of the terminal facility to the primary conveyance and from the primary conveyance to the animal holding area of the terminal facility as expeditiously as possible. Carriers and intermediate handlers holding any live nonhuman primate in an animal holding area of a terminal facility or in transporting any live nonhuman primate from the animal holding area of the terminal facility to the primary conveyance and from the primary conveyance to the animal holding area of the terminal facility, including loading and unloading procedures, shall provide the following:

(1) *Shelter from sunlight.* When sunlight is likely to cause overheating or discomfort, sufficient shade shall be provided to protect the live nonhuman primates from the direct rays of the sun and such live nonhuman primates shall not be subjected to surrounding air temperatures which exceed 29.5°C. (85°F.), and which shall be measured and read in the manner prescribed in § 3.90 of this Part, for a period of more than 45 minutes.

(2) *Shelter from rain or snow.* Live nonhuman primates shall be provided protection to allow them to remain dry during rain or snow.

(3) *Shelter from cold weather.* Transporting devices shall be covered to provide protection for live nonhuman primates when the outdoor air temperature falls below 10°C. (50°F.) and such live nonhuman primates shall not be subjected to surrounding air temperatures which fall below 7.2°C. (45°F.), and which shall be measured and read in the manner prescribed in § 3.90 of this part, for a period of more than 45 minutes unless such nonhuman primates are accompanied by a certificate of acclimation to lower temperatures as prescribed in § 3.85(c).

(b) Care shall be exercised to avoid handling of the primary enclosure in such a manner that may cause physical or emotional trauma to the live nonhuman primate contained therein.

(c) Primary enclosures used to transport any live nonhuman primate shall not be tossed, dropped, or needlessly tilted and shall not be stacked in a manner which may reasonably be expected to result in their falling.

[43 FR 21166, May 16, 1978, as amended at 43 FR 56217, Dec. 1, 1978]

Subpart E—Specifications for the Humane Handling, Care, Treatment, and Transportation of Marine Mammals

AUTHORITY: Secs. 3, 5, 6, 10, 11, 12, 16, 17, 21, 80 Stat. 351, 352, 353, 84 Stat. 1561, 1562, 1563, 1564, 90 Stat. 418, 419, 420, 423, (7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2144, 2146, 2147, 2151); 37 FR 28464, 28477, 38 FR 19141, unless otherwise noted.

SOURCE: 44 FR 36874, June 22, 1979, unless otherwise noted.

FACILITIES AND OPERATING STANDARDS

§ 3.100 Special considerations regarding compliance and/or variance.

(a) All persons subject to the Animal Welfare Act who maintain or otherwise handle marine mammals in captivity must comply with the provisions of this subpart, except that they may apply for and be granted a variance,[1]

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[1] Written permission from the Deputy Administrator to operate as a licensee or regis-

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by the Deputy Administrator, from one or more specified provisions of § 3.104. The provisions of this Subpart shall not apply, however, in emergency circumstances where compliance with one or more requirements would not serve the best interest of the marine mammals concerned.

(b) An application for a variance must be made to the Deputy Administrator in writing. The request must include:

(1) The species and number of animals involved,

(2) A statement from the attending veterinarian concerning the age and health status of the animals involved, and concerning whether the granting of a variance would be detrimental to the marine mammals involved,

(3) Each provision of the regulations that is not met,

(4) The time period requested for a variance,

(5) The specific reasons why a variance is requested, and

(6) The estimated cost of coming into compliance, if construction is involved.

(c) After receipt of an application for a variance, the Deputy Administrator may require the submission in writing of a report by two experts recommended by the American Association of Zoological Parks and Aquariums and approved by the Deputy Administrator concerning potential adverse impacts on the animals involved or on other matters relating to the effects of the requested variance on the health and well-being of such marine mammals. Such a report will be required only in those cases when the Deputy Administrator determines that such expertise is necessary to determine whether the granting of a variance would cause a situation detrimental to the health and well-being of the marine mammals involved. The cost of such report is to be paid by the applicant.

(d) Variances granted for facilities because of ill or infirm marine mammals that cannot be moved without placing their well-being in jeopardy, or for facilities within 0.3048 meters (1 foot) of compliance with any space requirement may be granted for up to the life of the marine mammals involved. Otherwise, variances shall be granted for a period not exceeding July 30, 1986, *Provided, however,* That under circumstances deemed justified by the Deputy Administrator, a maximum extension of 1 year may be granted to attain full compliance. A written request for the extension must be received by the Deputy Administrator by May 30, 1986. Consideration for extension by the Deputy Administrator will be limited to unforeseen or unusual situations such as when necessary public funds cannot be allocated in an appropriate time frame for a facility to attain full compliance by July 30, 1986.

(e) The Deputy Administrator shall deny any application for a variance if he determines that it is not justified under the circumstances or that allowing it will be detrimental to the health and well-being of the marine mammals involved.

(f) Any facility housing marine mammals that does not meet all of the space requirements as of July 30, 1984, must meet all of the requirements by September 28, 1984, or may operate without meeting such requirements until action is taken on an application for a variance if the application is submitted to the Deputy Administrator on or before September 28, 1984.

(g) A research facility may be granted a variance from specified requirements of this subpart when such variance is necessary for research purposes and is fully explained in the experimental design. Any time limitation stated in this section shall not be applicable in such case.

(Secs. 3, 5, 6, 10, 11, 12, 16, 17, 21, 80 Stat. 351, 352, 353, 84 Stat. 1561, 1562, 1563, 1564, 90 Stat. 418, 419, 420, 423; 7 U.S.C 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2144, 2146, 2147, 2151; 7 CFR 2.17, 2.51, 371.2(d))

[49 FR 26681, June 28, 1984]

§ 3.101 Facilities, general.

(a) *Construction requirements.* (1) Indoor and outdoor housing facilities for marine mammals shall be structurally sound and shall be maintained in

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trant under the Act without being in full compliance with one or more specified provisions of § 3.104.

good repair, to protect the animals from injury, to contain the animals, and to restrict the entrance of unwanted animals.

(2) All marine mammals shall be provided with protection from abuse and harassment by the viewing public by the use of a sufficient number of employees or attendants to supervise the viewing public, or by physical barriers, such as fences, walls, glass partitions, or distance, or both.

(3) Any primary enclosure pool, except for natural seawater pools subject to tidal action, shall be constructed of materials having a nonporous, waterproof finish, which facilitate proper cleaning and disinfection, and shall be maintained in good repair as part of a regular ongoing maintenance program. Any ramps or haul-out areas for primary enclosure pools, and any natural seawater pools subject to tidal action, shall be constructed of materials which facilitate proper cleaning and disinfection and shall be maintained in good repair as part of a regular ongoing maintenance program.

(4) Facilities which utilize natural water areas, such as tidal basins, bays, or estuaries (subject to natural tidewater action) used for housing marine mammals shall be exempt from the drainage requirements of paragraph (c)(1) of this section, but they must meet the minimum standards with regard to space, depth, and sanitation. The water must be monitored for coliforms and for ph and chemical content, if chemicals are added.

(b) *Water and power supply.* Reliable and adequate sources of water and electric power shall be provided by the facility housing marine mammals. Written contingency plans must be submitted to and approved by Veterinary Services regarding emergency sources of water and electric power in the event of failure of the primary sources, when such failure could reasonably be expected to be detrimental to the good health and well-being of the marine mammals housed therein.

(c) *Drainage.* (1) Adequate drainage shall be provided for all primary enclosure pools and shall be located so that all of the water contained in such pools may be rapidly eliminated when necessary for cleaning the pools or for other purposes. Drainage effluent from primary enclosure pools shall be disposed of in a manner that complies with all applicable Federal, State, and local pollution control laws.

(2) Drainage shall be provided for primary enclosures and areas immediately surrounding pools. Drains shall be located so as to rapidly eliminate excess water (except in pools). Such drainage effluent shall be disposed of in a manner that complies with all applicable Federal, State, and local pollution control laws.

(d) *Storage.* Supplies of food shall be stored in facilities which adequately protect such supplies from deterioration, molding, or contamination by vermin. Refrigerators and freezers shall be used for perishable food. No substances which are known to be or may be toxic or harmful to marine mammals shall be stored or maintained in the marine mammal food storage areas.

(e) *Waste disposal.* Provision shall be made for the removal and disposal of animal and food wastes, dead animals, trash, and debris. Disposal facilities shall be provided and operated in a manner which will minimize vermin infestation, odors, and disease hazards. All waste disposal procedures must comply with all applicable Federal, State, and local laws pertaining to pollution control, protection of the environment, and public health.

(f) *Washroom facilities.* Facilities such as washrooms, basins, showers, or sinks, shall be provided to maintain cleanliness among employees and attendants.

(Secs. 3, 5, 6, 10, 11, 12, 16, 17, 21, 80 Stat. 351, 352, 353, 84 Stat. 1561, 1562, 1563, 1564, 90 Stat. 418, 419, 420, 423; 7 U.S.C 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2144, 2146, 2147, 2151; 7 CFR 2.17, 2.51, 371.2(d))

[44 FR 36874, June 22, 1979, as amended at 44 FR 63492, Nov. 2, 1979; 49 FR 26682, June 28, 1984]

§ 3.102 Facilities, indoor.

(a) *Ambient temperature.* The air and water temperatures in indoor facilities shall be sufficiently regulated by heating or cooling to protect the marine mammals from extremes of temperature, to provide for their good health and well-being and to prevent discomfort, in accordance with the currently accepted practices as cited in appropriate professional journals or reference guides, depending upon the species housed therein. Rapid changes in air and water temperatures shall be avoided.

(b) *Ventilation.* Indoor housing facilities shall be ventilated by natural or artificial means to provide a flow of fresh air for the marine mammals and to minimize the accumulation of chlorine fumes, other gases, and objectionable odors. A vertical air space averaging at least 1.83 meters (6 feet) shall be maintained in all primary enclosures housing marine mammals, including pools of water.

(c) *Lighting.* Indoor housing facilities for marine mammals shall have ample lighting, by natural or artificial means, or both, of a quality, distribution, and duration which is appropriate for the species involved. Sufficient lighting must be available to provide uniformly distributed illumination which is adequate to permit routine inspections, observations, and cleaning of all parts of the primary enclosure including any den areas. The lighting shall be designed so as to prevent overexposure of the marine mammals contained therein to excessive illumination.[5]

§ 3.103 Facilities, outdoor.

(a) *Environmental temperatures.* Marine mammals shall not be housed in outdoor facilities unless the air and water temperature ranges which they may encounter during the period they are so housed do not adversely affect their health and comfort. A marine mammal shall not be introduced to an outdoor housing facility until it is acclimated to the air and water temperature ranges which it will encounter therein. The following requirements shall be applicable to all outdoor pools.

(1) The water surface of pools in outdoor primary enclosures housing polar bears and ice or cold water dwelling species of pinnipeds shall be kept sufficiently free of solid ice to allow for entry and exit of the animals.

(2) The water surface of pools in outdoor primary enclosures housing cetaceans and sea otters shall be kept free of ice.

(3) No sirenian or warm water dwelling species of pinnipeds or cetaceans shall be housed in outdoor pools where water temperature cannot be maintained within the temperature range to meet their needs.

(b) *Shelter.* Natural or artificial shelter which is appropriate for the species concerned, when the local climatic conditions are taken into consideration, shall be provided for all marine mammals kept outdoors to afford them protection from the weather or from direct sunlight.

§ 3.104 Space requirements.

(a) *General.* Primary enclosures, including pools of water housing marine mammals, shall comply with the minimum space requirements prescribed by this part. They shall be constructed and maintained so that the animals contained therein are provided with sufficient space, both horizontally and vertically so that they are able to make normal postural and social adjustments with adequate freedom of movement, in or out of the water. An exception to these requirements is provided for in § 3.110, "Veterinary care." Primary enclosures smaller than required by the standards are also allowed to be used for temporary holding purposes such as training and transfer. Such enclosures shall not be used for permanent housing purposes or for periods longer than specified by an attending veterinarian.

(b) *Cetaceans.* Primary enclosures housing cetaceans shall contain a pool of water and may consist entirely of a pool of water. In determining the minimum space required in a pool holding cetaceans, four factors must be satisfied. These are MHD, depth, volume, and surface area. For the purposes of this subpart, cetaceans are divided into Group I cetaceans and Group II cetaceans as shown in Table III in this section.

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[5] Lighting intensity and duration must be consistent with the general well-being and comfort of the animal involved. When possible, it should approximate the lighting conditions encountered by the animal in its natural environment. At no time shall the lighting be such that it will cause the animal discomfort or trauma.

(1)(i) *The required minimum horizontal dimension* (MHD) of a pool for Group I cetaceans shall be 7.32 meters (24.0 feet) or two times the average adult length of the longest species of Group I cetacean housed therein (as measured in a parallel or horizontal line, from the tip of its upper jaw, or from the most anterior portion of the head in bulbous headed animals, to the notch in the tail fluke[2]), whichever is greater; except that such MHD measurement may be reduced from the greater number by up to 20 percent if the amount of the reduction is added to the MHD at the 90-degree angle and if the minimum volume and surface area requirements are met based on an MHD of 7.32 meters (24.0 feet) or two times the average adult length of the longest species of Group I cetacean housed therein, whichever is greater.

(ii) The MHD of a pool for Group II cetaceans shall be 7.32 meters (24.0 feet) or four times the average adult length of the longest species of cetacean to be housed therein (as measured in a parallel or horizontal line from the tip of its upper jaw, or from the most anterior portion of the head in bulbous headed animals, to the notch in the tail fluke), whichever is greater; except that such MHD measurement may be reduced from the greater number by up to 20 percent if the amount of the reduction is added to the MHD at the 90-degree angle and if the minimum volume and surface area requirements are met based on an MHD of 7.32 meters (24.0 feet) or four times the average adult length of the longest species of Group II cetacean housed therein, whichever is greater.

(iii) In a pool housing a mixture of Group I and Group II cetaceans, the MHD shall be the largest required for any cetacean housed therein.

(iv) Once the required MHD has been satisfied, the pool size may be required to be adjusted to increase the surface area and volume when cetaceans are added. Examples of MHD and volume requirements for Group I cetaceans are shown in Table I, and for Group II cetaceans in Table II.

TABLE I.[1]—GROUP I CETACEANS

Representative average adult lengths		Minimum horizontal dimension (MHD)		Minimum required depth		Volume of water required for each additional cetacean in excess of two	
Meters	Feet	Meters	Feet	Meters	Feet	Cubic meters	feet
1.68	5.5	7.32	24	1.83	6	8.11	284.95
2.29	7.5	7.32	24	1.83	6	15.07	529.87
2.74	9.0	7.32	24	1.83	6	21.57	763.02
3.05	10.0	7.32	24	1.83	6	26.73	942.00
3.51	11.5	7.32	24	1.83	6	35.40	1,245.79
3.66	12.0	7.32	24	1.83	6	38.49	1,356.48
4.27	14.0	8.53	28	2.13	7	60.97	2,154.04
5.49	18.0	10.97	36	2.74	9	129.65	4,578.12
5.64	18.5	11.28	37	2.82	9.25	140.83	4,970.33
5.79	19.0	11.58	38	2.90	9.50	152.64	5,384.32
6.71	22.0	13.41	44	3.36	11	237.50	8,358.68
6.86	22.5	13.72	45	3.43	11.25	253.42	8,941.64
7.32	24.0	14.63	48	3.66	12	307.89	10,851.64
8.53	28.0	17.07	56	4.27	14	487.78	17,232.32

[1] All calculations are rounded off to the nearest hundredth. In converting the length of cetaceans from feet to meters, 1 foot equals .3048 meter. Due to rounding of meter figures as to the length of the cetacean, the correlation of meters to feet in subsequent calculations of MHD and additional volume of water required per cetacean, over two, may vary slightly from a strict

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[2] The body length of a *Monodon monoceros* (narwhale) is measured from the tip of the upper incisor tooth to the notch in the tail fluke. If the upper incisor is absent or does not extend beyond the front of the head, then it is measured like other cetaceans, from the tip of the upper jaw to the notch in the tail fluke. Immature males should be anticipated to develop the "tusk" (usually left incisor tooth) beginning at sexual maturity.

feet to meters ratio. Cubic meters is based on: 1 cubic foot = 0.0283 cubic meter.

TABLE II.[1]—GROUP II CETACEANS

Representative average adult length.		Minimum horizontal dimension (MHD)		Minimum required depth		Volume of water required for each additional cetacean in excess of four	
Meters	Feet	Meters	Feet	Meters	Feet	Cubic meters [1]	Cubic feet
1.52	5.0	7.32	24	1.83	6	13.28	471.00
1.68	5.5	7.32	24	1.83	6	16.22	569.91
1.83	6.0	7.32	24	1.83	6	19.24	678.24
2.13	7.0	8.53	28	1.83	6	26.07	923.16
2.29	7.5	9.14	30	1.83	6	30.13	1,059.75
2.44	8.0	9.75	32	1.83	6	34.21	1,205.76
2.59	8.5	10.36	34	1.83	6	38.55	1,361.19
2.74	9.0	10.97	36	1.83	6	43.14	1,526.04

[1] Converting cubic feet to cubic meters is based on: 1 cubic foot = 0.0283 of a cubic meter.

TABLE III.—AVERAGE ADULT LENGTHS OF MARINE MAMMALS MAINTAINED IN CAPTIVITY [1]

Species	Common name	Average adult length	
		In meters	In feet
Group I Cetaceans:			
Balaenoptera acutorostrata	Minke whale	8.50	27.9
Cephalorhynchus commersonii	Commerson's dolphin	1.52	5.0
Delphinapterus leucas	Beluga whale	4.27	14.0
Monodon monoceros	Narwhale	3.96	13.0
Globicephala melaena	Long-finned pilot whale	5.79	19.0
Globicephala macrorhynchus	Short-finned pilot whale	5.49	18.0
Grampus griseus	Risso's dolphin	3.66	12.0
Orcinus orca	Killer whale	7.32	24.0
Pseudorca carassidens	False killer whale	4.35	14.3
Tursiops truncatus (Atlantic)	Bottlenose dolphin	2.74	9.0
Tursiops truncatus (Pacific)	Bottlenose dolphin	3.05	10.0
Inia geoffrensis	Amazon porpoise	2.44	8.0
Phocoena phocoena	Harbor porpoise	1.68	5.5
Pontoporia blainvillei	Franciscana	1.52	5.0
Sotalia fluviatilis	Tucuxi	1.68	5.5
Platanista, all species	River dolphin	2.44	8.0
Group II Cetaceans:			
Delphinus delphis	Common dolphin	2.59	8.5
Feresa attenuata	Pygmy killer whale	2.44	8.0
Kogia breviceps	Pygmy sperm whale	3.96	13.0
Kogia simus	Dwarf sperm whale	2.90	9.5
Lagenorhynchus acutus	Atlantic white-sided dolphin	2.90	9.5
Lagenorhynchus cruciger	Hourglass dolphin	1.70	5.6
Lagenorhynchus obliquidens	Pacific white-sided dolphin	2.29	7.5
Lagenorhynchus albirostris	White-beaked dolphin	2.74	9.0
Lagenorhynchus obscurus	Duskey dolphin	2.13	7.0
Lissodelphis borealis	Northern right whale dolphin	2.74	9.0
Neophocaena phocaenoides	Finless porpoise	1.83	6.0
Peponocephala electra	Melon-headed whale	2.74	9.0
Phocoenoides dalli	Dall's porpoise	2.00	6.5
Stenella longirostris	Spinner dolphin	2.13	7.0
Stenella coeruleoalba	Striped dolphin	2.29	7.5
Stenella attenuata	Spotted dolphin	2.29	7.5
Stenella plagiodon	Spotted dolphin	2.29	7.5
Steno bredanensis	Rough-toothed dolphin	2.44	8.0

[1] This table contains the species of marine mammals known by the Department to be presently in captivity or that are likely to become captive in the future. Anyone who is subject to the Animal Welfare Act having species of marine mammals in captivity which are not included in this table should consult the Deputy Administrator with regard to the average adult length of such animals.

Species	Common name	Average adult length			
		In meters		In feet	
		Male	Female	Male	Female
Group I Pinnipeds:					
*Arctocephalus gazella***	Antarctic Fur Seal	1.80	1.20	5.9	3.9
*Arctocephalus tropicalis***	Amsterdam Island Fur Seal	1.80	1.45	5.9	4.75
*Arctocephalus australis***	South American Fur Seal	1.88	1.42	6.2	4.7
*Arctocephalus pusillis***	Cape Fur Seal	2.73	1.83	8.96	6.0
*Callorhinus ursinus***	Northern Fur Seal	2.20	1.45	7.2	4.75
*Eumetopias jubatus***	Steller's Sea Lion	2.86	2.40	9.4	7.9
Hydrurga leptonyx	Leopard Seal	2.90	3.30	9.5	10.8
*Mirounga angustirostris***	Northern Elephant Seal	3.96	2.49	13.0	8.2
*Mirounga leonina***	Southern Elephant Seal	4.67	2.50	15.3	8.2
*Odobenus rosmarus***	Walrus	3.15	2.60	10.3	8.5
*Otaria flavescens***	South American Sea Lion	2.40	2.00	7.9	6.6
Phoca caspica	Caspian Seal	1.45	1.40	4.75	4.6
Phoca fasciata	Ribbon Seal	1.75	1.68	5.7	5.5
Phoca larga	Harbor Seal	1.70	1.50	5.6	4.9
Phoca vitulina	Habor Seal	1.70	1.50	5.6	4.9
Zalophus californianus	California Sea Lion	2.24	1.75	7.3	5.7
*Halichoerus grypus***	Grar Seal	2.30	1.95	7.5	6.4
Phoca sibirica	Baikal Seal	1.70	1.85	5.6	6.1
Phoca groenlandica	Harp Seal	1.85	1.85	6.1	6.1
*Leptonychotes weddelli***	Weddell Seal	2.90	3.15	9.5	10.3
*Lobodon carcinophagus***	Crabeater Seal	2.21	2.21	7.3	7.3
*Ommatophoca rossi***	Ross Seal	1.99	2.13	6.5	7.0
Group II Pinnipeds:					
Erignathus barbatus	Bearded Seal	2.33	2.33	7.6	7.6
Phoca hispida	Ringed Seal	1.35	1.30	4.4	4.3
Cystophora cristata	Hooded Seal	2.60	2.00	8.5	6.6

NOTE.—** Any Group I animals maintained together will be considered as Group II when the animals maintained together include two or more sexually mature males from species marked with a double asterisk (**) regardless of whether the sexually mature males from the same species.

Species	Common name	Average adult length	
		In meters	In feet
Sirenia:			
Dugong dugong	Dugong	3.35	11.0
Trichechus manatus	West Indian Manatee	3.51	11.5
Trichechus inunguis	Amazon Manatee	2.44	8.0
Mustelidae:			
Enhydra lutris	Sea Otter	1.25	4.1

(2) *The minimum depth requirement* for primary enclosure pools for all cetaceans shall be one-half the average adult length of the longest species to be housed therein, regardless of Group I or Group II classification, or 1.83 meters (6.0 feet), whichever is greater, and can be expressed as $d=L/2$ or 6 feet, whichever is greater. Those parts of the primary enclosure pool which do not meet the minimum depth requirement cannot be included when calculating space requirements for cetaceans.

(3) *Pool volume.* A pool of water housing cetaceans which satisfies the MHD and which meets the minimum depth requirement, will have sufficient volume and surface area to hold up to two Group I cetaceans or up to four Group II cetaceans. If additional cetaceans are to be added to the pool, the volume as well as the surface area may have to be adjusted to allow for additional space necessary for such cetaceans. See Tables I, II, and IV for volumes and surface area requirements. The additional volume needed shall be based on the number and kind of cetaceans housed therein and shall be determined in the following manner.

(i) The minimum volume of water required for up to two Group I cetaceans is based upon the following formula:

$$\text{Volume} = \left(\frac{\text{MHD}}{2}\right)^2 \times 3.14 \times \text{depth}$$

When there are more than two Group I cetaceans housed in a primary enclosure pool, the additional volume of water required for each additional Group I cetacean in excess of two is based on the following formula:

$$\text{Volume} = \frac{(\text{Average Adult Length})^2}{2} \times 3.14 \times \text{depth}$$

See Table I for required volumes.

(ii) The minimum volume of water required for up to four Group II cetaceans is based upon the following formula:

$$\text{Volume} = \left(\frac{\text{MHD}}{2}\right)^2 \times 3.14 \times \text{depth}$$

When there are more than four Group II cetaceans housed in a primary enclosure pool, the additional volume of water required for each additional Group II cetacean in excess of four is based on the following formula:

$$\text{Volume} = (\text{Average Adult Length})^2 \times 3.14 \times \text{depth}$$

See Table II for required volumes.

(iii) When a mixture of both Group I and Group II cetaceans are housed together, the MHD must be satisfied as stated in § 3.104(b)(1), and the minimum depth must be satisfied as stated in § 3.104(b)(2). Based on these figures, the resulting volume must then be calculated

$$\text{Volume} = \left(\frac{\text{MHD}}{2}\right)^2 \times 3.14 \times \text{depth}$$

Then the volume necessary for the cetaceans to be housed in the pool must be calculated (by obtaining the sum of the volumes required for each animal). If this volume is greater than that obtained by using the MHD and depth figures, then the additional volume required may be added by enlarging the pool in its lateral dimensions or by increasing its depth, or both. The minimum surface area requirements discussed next must also be satisfied.

(4)(i) *The minimum surface area* requirements for each cetacean housed in a pool, regardless of Group I or Group II classification, are calculated as follows:

$$\text{Surface Area} = \left(\frac{\text{average adult body length}}{2}\right)^2 \times 3.14 \times 1.5, \quad \text{or:}$$

$$\text{SA} = (\text{L}/2)^2 \times 3.14 \times 1.5$$

In a pool containing more than two Group I cetaceans or more than four Group II cetaceans,[8] the additional surface area which may be required when animals are added must be calculated for each such animal.

(ii) When a mixture of Group I and Group II cetaceans are to be housed in a pool, the required MHD, depth, and volume must be met. Then the required surface area must be determined for each animal in the pool. The sum of these surface areas must then be compared to the surface area which is obtained by a computation based on the required MHD of the pool.[9] The larger of the two figures represents the surface area which is required for a pool housing a mixture of Group I and Group II cetaceans. Pool surfaces where the depth does not meet the minimum requirements cannot be used in determining the required surface area.

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[8] A pool containing up to two Group I cetaceans or up to four Group II cetaceans which meets the required MHD and depth will have the necessary surface area and volume required for the animals contained therein.

[9] Since the MHD represents the diameter of a circle, the surface area based on the MHD is calculated by use of the following formula:

$$SA = \pi \times \left(\frac{MHD}{2}\right)^2.$$

(iii) Surface area requirements are given in Table IV.

TABLE IV—MINIMUM SURFACE AREA REQUIRED FOR EACH CETACEAN

Average adult length of each cetacean		Surface area required for each cetacean	
Meters	Feet	Sq. meters[1]	Sq. feet
1.68	5.5	3.31	35.62
2.13	7.0	5.36	57.70
2.29	7.5	6.15	66.23
2.59	8.5	7.90	85.07
2.74	9.0	8.86	95.38
3.05	10.0	10.94	117.75
3.51	11.5	14.47	155.72
3.66	12.0	15.75	169.56
4.27	14.0	21.44	230.79
5.49	18.0	35.44	381.51
5.64	18.5	37.43	403.00
5.79	19.0	39.49	425.08
6.71	22.0	52.94	569.91
6.86	22.5	55.36	596.11
7.32	24.0	63.01	678.24
8.53	28.0	85.76	923.16

[1] Square meter = square feet/9 × 0.8361.

(c) *Sirenians.* Primary enclosures housing sirenians shall contain a pool of water and may consist entirely of a pool of water.

(1) The required MHD of a primary enclosure pool for sirenians shall be two times the average adult length of the longest species of sirenian to be housed therein. Calculations shall be based on the average adult length of such sirenians as measured in a horizontal line from the tip of the muzzle to the notch in the tail fluke of dugongs and from the tip of the muzzle to the most distal point in the rounded tail of the manatee.

(2) The minimum depth requirements for primary enclosure pools for all sirenians shall be one-half the average adult length of the longest species to be housed therein, or 1.52 meters (5.0 feet), whichever is greater. Those parts of the primary enclosure pool which do not meet the minimum depth requirements cannot be included when calculating space requirements for sirenians.

(3) A pool which satisfies the required MHD and depth shall be adequate for one or two sirenians. Volume and surface area requirements for additional animals shall be calculated using the same formula as for Group I cetaceans, except that the figure for depth requirement for sirenians shall be one-half the average adult length or 1.52 meters (5.0 feet), whichever is greater.

(d) *Pinnipeds.* (1) Primary enclosures housing pinnipeds shall contain a pool of water and a dry resting or social activity area that must be close enough to the surface of the water to allow easy access for entering or leaving the pool. For the purposes of this subpart, pinnipeds have been divided into Group I pinnipeds and Group II pinnipeds as shown in Table III in this section. In certain instances some Group I pinnipeds shall be considered as Group II pinnipeds. (See Table III).

(2) The minimum size of the dry resting or social activity area of the primary enclosure for pinnipeds (exclusive of the pool of water) shall be based on the average adult length of each pinniped contained therein, as measured in a horizontal or extended position in a straight line from the tip of its nose to the tip of its tail. The minimum size of the dry resting or social activity area shall be computed using the following methods:

(i) *Group I pinnipeds.* Square the average adult length of each pinniped to be contained in the primary enclosure. Add the figures obtained for each of the pinnipeds in the primary enclosure to determine the dry resting or social activity area required for such pinnipeds. If only a single Group I pinniped is maintained in the primary enclosure, the minimum dry resting or social activity area shall be twice the square of the average adult length of that single Group I pinniped. Examples:

(average adult length)^2 of 1st Group I pinniped + (average adult length)^2 of 2nd Group I pinniped = Total DRA for two pinnipeds

DRA for one pinniped = 2 × (average adult length of Group I pinniped)^2

(ii) *Group II pinnipeds.* List all pinnipeds contained in a primary enclosure by average adult length in descending order from the longest species of pinniped to the shortest species of pinniped. Square the average adult length of each pinniped. Multiply the average adult length squared of the longest pinniped by 1.5, the second longest by 1.4, the third longest by 1.3, the fourth longest by 1.2, and the fifth longest by 1.1, as indicated in the following example. Square the average adult length of the sixth pinniped and each additional pinniped. Add the figures obtained for all the pinnipeds in the primary enclosure to determine the required minimum dry resting or social activity area required for such pinnipeds. If only a single Group II pinniped is maintained in the primary enclosure, the minimum dry resting or social activity area must be computed for a minimum of two pinnipeds.

Examples: DRA for 1 Group II Pinniped = [(Average adult length)^2 × 1.5] + [(Average adult length)^2 × 1.4]

1st pinniped (avg. adult length)^2 × 1.5 = social and DRA required
2nd pinniped (avg. adult length)^2 × 1.4 = social and DRA required
3rd pinniped (avg. adult length)^2 × 1.3 = social and DRA required
4th pinniped (avg. adult length)^2 × 1.2 = social and DRA required
5th pinniped (avg. adult length)^2 × 1.1 = social and DRA required
Each pinniped over 5 (avg. adult length)^2 = social and DRA required

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Total minimum social activity and dry resting area required for all pinnipeds housed in a primary enclosure.

If all the pinnipeds in the primary enclosure are of the same species, the same descending order of calculation shall apply. Example: Hooded seal—average adult length of male = 8.5 feet and female = 6.6 feet. In a primary enclosure containing 2 males and 2 females, the social or DRA required would be the sum of $[(8.5)^2 \times 1.5] + [(8.5)^2 \times 1.4] + [(6.6)^2 \times 1.3] + [(6.6)^2 \times 1.2]$. If two or more sexually mature males are maintained together in a primary enclosure, the dry resting or social activity area shall be divided into two or more separate areas with sufficient visual barriers (such as fences, rocks, or foliage) to provide relief from aggressive animals.

(iii) *Mixture of Group I and Group II pinnipeds.* In a primary enclosure where a mixture of Group I and Group II pinnipeds is to be housed, the dry resting or social activity area shall be calculated as for Group II pinnipeds. The dry resting or social activity area shall be divided into two or more separate areas with sufficient visual barriers (such as fences, rocks, or foliage) to provide relief from aggressive animals.

(3)(i) The minimum surface area of a pool of water for pinnipeds shall be at least equal to the dry resting or social activity area required.

(ii) The MHD of the pool shall be at least one and one-half (1.5) times the average adult length of the largest species of pinniped to be housed in the enclosure; except that such MHD measurement may be reduced by up to 20 percent if the amount of the reduction is added to the MHD at the 90-degree angle.

(iii) The pool of water shall be at least 0.91 meters (3.0 feet) deep or one-half the average adult length of the longest species of pinniped contained therein, whichever is greater. Parts of the pool that do not meet the minimum depth requirement cannot be used in the calculation of the dry resting and social activity area, or as part of the MHD or required surface area of the pool.

(e) *Polar bears.* Primary enclosures housing polar bears shall consist of a pool of water, a dry resting and social activity area, and a den. A minimum of 37.16 square meters (400 square feet) of dry resting and social activity area shall be provided for up to two polar bears, with an additional 3.72 square meters (40 square feet) of dry resting and social activity area for each additional polar bear. The dry resting and social activity area shall be provided with enough shade to accommodate all of the polar bears housed in such primary enclosure at the same time. The pool of water shall have an MHD of not less than 2.44 meters (8.0 feet) and a surface area of at least 8.93 square meters (96.0 square feet) with a minimum depth of 1.52 meters (5.0 feet) with the exception of any entry and exit area. This size pool shall be adequate for two polar bears. For each additional bear, the surface area of the pool must be increased by 3.72 square meters (40 square feet). In measuring this additional surface area, parts of the pool which do not meet minimum depth cannot be considered. The den shall be at least 1.83 meters (6 feet) in width and depth and not less than 1.52 meters (5 feet) in height. It will be so positioned that the viewing public shall not be visible from the interior of the den. A separate den shall be provided for each adult female of breeding age which is permanently housed in the same primary enclosure with an adult male of breeding age. Female polar bears in traveling acts or shows must be provided a den when pregnancy has been determined.

(f) *Sea otters.* (1) Primary enclosures for sea otters shall consist of a pool of water and a dry resting area. The MHD of the pool of water for sea otters shall be at least three times the average adult length of the sea otter contained therein (measured in a horizontal line from the tip of its nose to the tip of its tail) and the pool shall be not less than .91 meters (3.0 feet) deep. When more than two sea otters are housed in the same primary enclosure, additional dry resting area as well as pool volume is required to accommodate the additional sea otters. (See Table V).

(2) The minimum volume of water required for a primary enclosure pool for sea otters shall be based on the sea otter's average adult length. The minimum volume of water required in the pool shall be computed using the following method: Multiply the square of the sea otter's average adult length by 3.14 and then multiply the total by 0.91 meters (3.0 feet). This volume is satisfactory for one or two otters. To calculate the additional volume of water for each additional sea otter above two in a primary enclosure, multiply one-half of the square of the sea otter's average adult length by 3.14, then multiply by 0.91 meters (3.0 feet). (See Table V).

(3) The minimum dry resting area required for one or two sea otters shall be based on the sea otter's average adult length. The minimum dry resting area for one or two sea otters shall be computed using the following method: Square the average adult length of the sea otter and multiply the total by 3.14. When the enclosure is to contain more than two sea otters, the dry resting area for each additional animal shall be computed by multiplying one-half of the sea otter's average adult length by 3.14. Using 1.25 meters or 4.1 feet (the average adult length of a sea otter), the calculations for additional space will result in the following figures:

TABLE V.—ADDITIONAL SPACE REQUIRED FOR EACH SEA OTTER WHEN MORE THAN TWO IN A PRIMARY ENCLOSURE

Average adult length of sea otter		Resting area		Pool Volume	
Meters	Feet	Square meters	Square Feet	Cubic meters	Cubic feet
1.25	4.1	1.96	6.44	2.23	79.17

(Secs. 3, 5, 6, 10, 11, 12, 16, 17, 21, 80 Stat. 351, 352, 353, 84 Stat. 1561, 1562, 1563, 1564, 90 Stat. 418, 419, 420, 423; 7 U.S.C 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2144, 2146, 2147, 2151; 7 CFR 2.17, 2.51, 371.2(d))

[44 FR 36874, June 22, 1979, as amended at 45 FR 63261, Sept. 24, 1980; 49 FR 26682, 26685, June 28, 1984; 49 FR 27922, July 9, 1984]

ANIMAL HEALTH AND HUSBANDRY STANDARDS

§ 3.105 Feeding.

(a) The food for marine mammals shall be wholesome, palatable, and free from contamination, and shall be of sufficient quantity and nutritive value to maintain all of the marine mammals in a state of good health. The diet shall be prepared with consideration for age, species, condition, size, and type of marine mammal being fed. Marine mammals shall be offered food at least once a day, except as directed by veterinary treatment or professionally accepted practices.

(b) Food receptacles, if used, shall be located so as to be accessible to all marine mammals in the same primary enclosure and shall be placed so as to minimize contamination of the food contained therein. Such food receptacles shall be cleaned and sanitized after each use.

(c) Food, when given to each marine mammal individually, shall be given by an employee or attendant responsible to management who has the necessary knowledge to assure that each marine mammal receives an adequate quantity of food to maintain it in good health. Such employee or attendant is required to have the ability to recognize deviations from a normal state of good health in each marine mammal so that the food intake can be adjusted accordingly. Public feeding shall be only permitted if it is done in the presence and under the supervision of a uniformed employee or attendant. Such employee or attendant must assure that the marine mammals are receiving the proper amount and type of food. Only food supplied by the facility where the marine mammals are kept shall be fed to such mammals by the public.

(d) Food preparation and handling shall be conducted so as to minimize bacterial or chemical contamination and to assure the wholesomeness and nutritive value of the food. Frozen fish or other frozen food shall be stored in freezers which are maintained at a maximum temperature of −18°C. (0°F.). The length of time food is stored and the method of storage, as well as the thawing of frozen food, shall be conducted in a manner which will minimize contamination and which will assure that the food retains nutritive value and wholesome quality. The thawed product shall be kept iced or refrigerated until a reasonable time before feeding. All foods shall be fed to the marine mammals within 24 hours following the removal of such foods from the freezers for thawing.

§ 3.106 Water quality.

(a) *General.* The primary enclosure shall not contain water which would be detrimental to the health of the marine mammal contained therein.

(b) *Bacterial standards.* (1) The coliform bacteria count of the primary enclosure pool shall not exceed 1,000 MPN (most probable number) per 100 ml. of water. Should a coliform bacterial count exceed 1,000 MPN, two subsequent samples may be taken at 48-hour intervals and averaged with the first sample. If such average count does not fall below 1,000 MPN, then the water in the pool shall be deemed unsatisfactory, and the condition must be corrected immediately.

(2) When the water is chemically treated, the chemicals shall be added so as not to cause harm or discomfort to the marine mammals.

(3) Water samples shall be taken and tested at least weekly for coliform count and at least daily for pH and any chemical additives (e.g. chlorine and copper) that are added to the water to maintain water quality standards. Facilities using natural seawater shall be exempt from pH and chemical testing unless chemicals are added to maintain water quality. However, they are required to test for coliforms. Records must be kept documenting the time when all such samples were taken and the results of the sampling. Records of all such test results shall be maintained by management for a 1-year period and must be made available for inspection purposes on request.

(c) *Salinity.* Primary enclosure pools of water shall be salinized for marine cetaceans as well as for those other marine mammals which require salinized water for their good health and well-being. The salinity of the water in such pools shall be maintained within a range of 15-36 parts per thousand.

(d) *Filtration and water flow.* Water quality must be maintained by filtration, chemical treatment, or other means so as to comply with the water quality standards specified in this section.

§ 3.107 Sanitation.

(a) *Primary enclosures.* (1) Animal and food waste in areas other than the pool of water shall be removed from the primary enclosure at least daily, and more often when necessary to prevent contamination of the marine mammals contained therein and to minimize disease hazards.

(2) Particulate animal and food waste, trash, or debris that enter the primary enclosure pool of water shall be removed as often as necessary to maintain the required water quality and to prevent health hazards to the marine mammals contained therein.

(3) The wall and bottom surfaces of the primary enclosure pool of water shall be cleaned as often as necessary to maintain proper water quality.

(b) *Food preparation areas and food receptacles.* Containers, such as buckets, tubs, and tanks, as well as utensils, such as knives and cutting boards, or any other equipment which has been used for holding, thawing or preparing food for marine mammals shall be cleaned and sanitized after each feeding, if the marine mammals are fed once a day, and at least daily if the marine mammals are fed more than once a day. Kitchens and other food handling areas where animal food is prepared shall be cleaned at least once daily and sanitized at least once every week. Sanitizing shall be accomplished by washing with hot water (82° C., 180° F., or higher) and soap or detergent in a mechanical dishwasher, or by washing all soiled surfaces with a detergent solution followed by a safe and effective disinfectant, or by cleaning all soiled surfaces with live steam. Substances such as cleansing and sanitizing agents, pesticides, and other potentially toxic agents must be stored in properly labeled containers away from food preparation surface areas.

(c) *Housekeeping.* Buildings and grounds, as well as exhibit areas, shall be kept clean and in good repair. Fences shall be maintained in good repair. Primary enclosures housing marine mammals shall not have any loose objects, sharp projections, and/or edges which may cause injury or trauma to the marine mammals contained therein.

(d) *Pest control.* A safe and effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained. Insecticides or other such chemical agents shall not be applied in a primary enclosure housing marine mammals except when deemed essential by an attending veterinarian.

§ 3.108 Employees or attendants.

A sufficient number of adequately trained employees or attendants responsible to management shall be utilized to maintain the prescribed level of husbandry practices set forth in this subpart. Such practices shall be conducted under the supervision of a marine mammal caretaker who has a background in marine mammal husbandry and care. Training of marine mammals shall be done by or under the direct supervision of experienced trainers without physical punishment or abuse being used or inflicted upon the marine mammals.

§ 3.109 Separation.

Marine mammals which are not compatible shall not be housed in the same enclosure. Marine mammals shall not be housed near animals that would cause them stress or discomfort, or interfere with their good health. Captive marine mammals must be given access to other animals except when they are temporarily maintained in isolation for such purposes as medical treatment or training and given special attention.

§ 3.110 Veterinary care.

(a) Programs of disease prevention, parasite control, euthanasia, and adequate veterinary care for all marine mammals shall be established and maintained under the supervision of an attending veterinarian.

(b) Marine mammals shall be observed daily by the person in charge of the care of the marine mammals or by someone working under his direct supervision. Sick or diseased, stressed, injured, or lame marine mammals shall be provided with adequate veterinary care or humanely destroyed, when necessary, unless such action is inconsistent with the research purposes for which the marine mammal was obtained and is being held.

(c)(1) In the case of a research facility, the program of adequate veterinary care shall include the appropriate use of anesthetic, analgesic, for tranquilizing drugs, when such use would be proper in the opinion of the attending veterinarian of the research facility. The use of these three classes of drugs shall be in accordance with currently accepted veterinary medical practices. The drugs used shall be those which are expected to produce in the individual subject animal as high a level of tranquilization, anesthesia, or analgesia as is consistent with the protocol or design of the experiment.

(2) It shall be incumbent upon each research facility through its Animal Care Committee and attending veterinarian to provide guidelines and consultation to research personnel with respect to the type and amount of tranquilizers, anesthetics, or analgesics recommended as being appropriate for each species of marine mammals used by that institution.

(d) Newly acquired marine mammals shall be isolated from resident marine mammals until such newly acquired marine mammals can be reasonably determined to be in good health. Any communicable disease condition in a newly acquired marine mammal must be remedied before it is placed with other resident marine mammals.

(e) Any primary enclosure containing a marine mammal with an infectious or contagious disease shall be cleaned and sanitized in the manner prescribed by the attending veterinarian. No additional animals shall be introduced into the primary enclosure prior to such cleaning and sanitizing procedures. Any marine mammal exposed to a diseased animal shall be isolated for observation for an appropriate period of time as determined by the attending veterinarian.

(f) Temporary holding facilities with adequately and properly designed pools, tanks, restraining devices or primary enclosures shall be provided for isolation, medication, treatment, and other purposes such as transfer and training of marine mammals. The pools, tanks and primary enclosures may be less than minimum size in both lateral dimensions and depth when used in special situations when prescribed by the professional staff for temporary usage.

(g) A complete necropsy must be conducted by or under the direct supervision of a veterinarian on all marine mammals that die in captivity. A necropsy report must be prepared by the veterinarian listing all pathologic lesions observed and giving the apparent cause of death. All diagnostic tests conducted on post mortem specimens shall be listed in the report, and the results of each test recorded. The management of the facility, at which the marine mammal died, must maintain these necropsy records for a period of 3 years and present them to Department inspectors when requested.

§ 3.111 Handling.

(a) Handling marine mammals shall be done as expeditiously and carefully as possible in a manner that does not cause unnecessary discomfort, overheating, behavioral stress, or physical harm. Care should also be exercised to avoid harm to the handlers of such marine mammals.

(b) Marine mammals shall only be displayed for periods of time and under conditions consistent with their good health, and well-being. A responsible uniformed employee or attendant must be present at all times during periods of public contact.

(c) During public display, all marine mammals must be handled so that there is minimal risk of harm to the public or the marine mammal, with sufficient distance allowed, or barriers placed between the marine mammal and the viewing public to assure safety to both the public and the marine mammal. Performing marine mammals shall be allowed a rest period between performances at least equal to the time for one performance.

TRANSPORTATION STANDARDS

§ 3.112 Consignments to carriers and intermediate handlers.

(a) Carriers and intermediate handlers shall not accept any marine mammal presented by any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or any State or local government for shipment, in commerce, more than 4 hours prior to the scheduled departure of the primary conveyance on which it is to be transported: *Provided, however,* That the carrier or intermediate handler and any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States of any State or local government may mutually agree to extend the time of acceptance to not more than 6 hours if specific prior scheduling of the animal shipment to destination has been made.

(b) Any carrier or intermediate handler shall only accept for transportation or transport, in commerce, any marine mammal in a primary enclosure which conforms to the requirements set forth in § 3.113 of the standards: *Provided, however,* That any carrier or intermediate handler may accept for transportation or transport, in commerce, any marine mammal consigned by any department, agency, or instrumentality of the United States having laboratory animal facilities or exhibiting animals or any licensed or registered dealer, research facility, exhibitor, or operator of an auction sale if the consignor furnishes to the carrier or intermediate handler a certificate, signed by the consignor, stating that the primary enclosure complies with § 3.113 of the standards, unless such primary enclosure is obviously defective or damaged and it is apparent that it cannot reasonably be expected to contain the marine mammal without causing suffering or injury to such marine mammal. A copy of such certificate shall accompany the shipment to destination. The certificate shall include at least the following information:

(1) Name and address of the consignor;

(2) The number of animals in the primary enclosure(s);

(3) A certifying statement (e.g., "I hereby certify that the ——— (number) primary enclosure(s) which are used to transport the animal(s) in this shipment complies (comply) with USDA standards for primary enclosures (9 CFR Part 3)."); and

(4) The signature of the consignor, and date.

(c) Carriers or intermediate handlers whose facilities fail to meet the minimum temperature allowed by the standards may accept for transportation or transport, in commerce, any marine mammal consigned by any department, agency, or instrumentality of the United States or of any State or local government, or by any person (including any licensee or registrant under the Act, as well as any private individual) if the consignor furnishes to the carrier or intermediate handler a certificate executed by a veterinarian accredited by this Department pursuant to Part 160 of this title on a specified date which shall not be more than 10 days prior to delivery of such animal for transportation in commerce, stating that such marine mammal is acclimated to air temperatures lower than those prescribed in §§ 3.117 and 3.118. A copy of such certificate shall accompany the shipment to destination. The certificate to include at least the following information:

(1) Name and address of the consignor;

(2) The number of animals in the shipment;

(3) A certifying statement (e.g., "I hereby certify that the animal(s) in this shipment is (are), to the best of my knowledge, acclimated to air temperatures lower than 7.2° C. (45° F.)"); and

(4) The signature of the USDA accredited veterinarian, assigned accreditation number, and date.

(d) Carriers and intermediate handlers shall attempt to notify the consigned at least once in every 6-hour period following the arrival of any marine mammals at the animal holding area of the terminal cargo facility. The time, date, and method of each attempted notification and the final notification to the consignee and the name of the person notifying the consignee shall be recorded on the copy of the shipping document retained by the carrier or intermediate handler and on a copy of the shipping document accompanying the animal shipment.

[44 FR 36874, June 22, 1979, as amended at 44 FR 63493, Nov. 2, 1979]

§ 3.113 Primary enclosures used to transport marine mammals.

No dealer, research facility, exhibitor, or operator of an auction sale shall offer for transportation or transport, in commerce, any marine mammal in a primary enclosure which does not conform to the following requirements:

(a) Primary enclosures, which are used to transport marine mammals other than cetaceans and sirenians, shall (1) be constructed from materials of sufficient structural strength to contain the marine mammals; (2) be constructed from material that is durable, nontoxic, and cannot be chewed and/or swallowed; (3) be able to withstand the normal rigors of transportation; (4) have interiors which are free from any protrusions that could be injurious to the marine mammals contained therein; (5) be constructed so that no parts of the contained marine mammals shall be exposed to the outside of the enclosures in such a way which may cause injury to the animals or to persons who are nearby or who handle the enclosures; (6) have openings which provide access into the enclosures which shall be secured with locking devices of a type which cannot be accidentally opened; (7) have such openings located in a manner which makes them easily accessible at all times for emergency removal of any live marine mammal contained therein; (8) have air inlets at heights which will provide cross ventilation at all levels (particularly when the marine mammals are in a prone position) and located on all four sides of the enclosures, and such ventilation openings shall be not less than 16 percent of the total surface area of each side of the enclosures; (9) have projecting rims or other devices placed on the ends and sides of any enclosures which have ventilation openings to provide a minimum air circulation space of 1.9 centimeters (0.75 inches) between the enclosures and any adjacent cargo or conveyance wall; and (10) be equipped with adequate handholds or other devices on the exterior of the enclosures which shall enable them to be lifted without unnecessary tilting and which will ensure that the persons handling the enclosures will not come in contact with any marine mammal contained therein.

(b) Straps, slings, harnesses, or other devices, if used for body support or restraint, when transporting marine mammals such as cetaceans and sirenians shall (1) be designed so as not to prevent access to such mammals by attendants during transportation for the purpose of administering in transit care; (2) be equipped with special padding to prevent trauma or injury at critical weight pressure points on the body of the marine mammals; and (3) be capable of keeping the animals from thrashing about and causing injury to themselves or their attendants, and yet be adequately designed so as not to cause injury to the animals.

(c) Primary enclosures used to transport live marine mammals shall be large enough to assure that (1) in the case of polar bears and sea otters, there is sufficient space to turn about freely in a stance whereby all four feet are on the floor and the animal can sit in an upright position and lie in a natural position; (2) in the case of pinnipeds, each animal has sufficient space to lie in a natural position; and (3) in the case of cetaceans and sirenians, each animal has sufficient space for support of its body in slings, harnesses, or other supporting devices, if used (as prescribed in paragraph (b) of this section) without causing injury to such cetaceans or sirenians due to contact with the primary enclosure: *Provided, however,* That certain species may be restricted in their movements according to professionally acceptable standards when such freedom of movement would constitute a danger to the animals, their handlers, or other persons.

(d) Marine mammals transported in the same primary enclosure shall be of the same species and maintained in compatible groups. Marine mammals which have not reached puberty shall not be transported in the same primary enclosure with adult marine mammals other than their dams. Socially dependent animals (e.g., sibling, dam, and other members of a family group) must be allowed visual and olfactory contact. Female marine mammals shall not be transported in the same primary enclosure with any mature male marine mammals.

(e) Primary enclosures used to transport marine mammals as provided in this section shall have solid bottoms to prevent leakage in shipment and shall be cleaned and sanitized in a manner prescribed in § 3.107 of the standards, if previously used. Such primary enclosures shall contain clean litter of a suitable absorbent material, which is safe and nontoxic to the marine mammals contained therein, in sufficient quantity to absorb and cover excreta, unless the animals are on wire or other nonsolid floors.

(f) Primary enclosures used to transport marine mammals, except where such primary enclosures are permanently affixed in the animal cargo space of the primary conveyance, shall be clearly marked on top and on one or more sides with the words "Live Animal" or "Wild Animal", whichever is appropriate, in letters not less than 2.5 centimeters (1 inch) in height, and with arrows or other markings, to indicate the correct upright position of the container.

(g) Documents accompanying the shipment shall be attached in an easily accessible manner to the outside of a primary enclosure which is part of such shipment.

(h) When a primary enclosure is permanently affixed within the animal cargo space of the primary conveyance so that the front opening is the only source of ventilation for such primary enclosure, the front opening shall open directly to the outside or to an unobstructed aisle or passageway within the primary conveyance. Such front ventilation opening shall be at least 90 percent of the total surface area of the front wall of the primary enclosure and covered with bars, wire mesh, or smooth expanded metal.

§ 3.114 Primary conveyances (motor vehicle, rail, air and marine).

(a) The animal cargo space of primary conveyances used in transporting live marine mammals shall be constructed in a manner which will protect the health and assure the safety and comfort of the marine mammals contained therein at all times.

(b) The animal cargo space shall be constructed and maintained in a manner which will prevent the ingress of engine exhaust fumes and gases in excess of that ordinarily contained in the passenger compartments.

(c) No marine mammal shall be placed in an animal cargo space that does not have a supply of air sufficient for normal breathing for each live animal contained therein, and the primary enclosures shall be positioned in the animal cargo spaces of primary conveyances in such a manner that each marine mammal contained therein shall have access to sufficient air for normal breathing.

(d) Primary enclosures shall be positioned in primary conveyances in such a manner that in an emergency the live marine mammals can be removed from the conveyances as soon as possible.

(e) The interiors of animal cargo spaces in primary conveyances shall be kept clean.

(f) Live marine mammals shall not knowingly be transported with any material, substance or device which may be injurious to the health and well-being of such marine mammals unless proper precaution is taken to prevent such injury.

§ 3.115 Food and water requirements.

(a) Those marine mammals which require drinking water shall be offered potable water within 4 hours prior to being transported in commerce or offered for transportation in commerce. Such marine mammals shall be watered as often as necessary and appropriate to the species involved to prevent excessive dehydration which would jeopardize the good health and well-being of the animals.

(b) Marine mammals shall not be transported for more than a period of 36 hours without being offered food. When an employee or attendant is required to accompany a shipment of marine mammals, as provided in § 3.116 of these standards, such marine mammals shall be fed during transit when necessary to provide for their good health and well-being.

§ 3.116 Care in transit.

(a) An employee or attendant of the shipper or receiver of any marine mammal being transported, in commerce, knowledgeable in the area of marine mammal care, shall accompany cetaceans, sirenians, pinnipeds, and sea otters during periods of transportation to provide for their good health and well-being, to observe such marine mammals and to determine whether they need veterinary care and to obtain any needed veterinary care as soon as possible.

(b) An employee or attendant of the shipper or receiver of cetaceans or sirenians being transported, in commerce, shall provide for such cetaceans and sirenians during periods of transport by (1) keeping the skin moist or preventing the drying of the skin by such methods as intermittent spraying of water or application of a nontoxic emollient, such as lanolin; (2) assuring that the pectoral flippers shall be allowed freedom of movement at all times; (3) making adjustments in the position of such marine mammals when necessary to prevent necrosis of the skin at weight pressure points; and (4) calming such marine mammals to avoid struggling, thrashing, and other unnecessary activity which may cause overheating or physical trauma. No cetacean or sirenian in need of veterinary care shall be transported in commerce, unless such transportation is for the purpose of obtaining such care.

(c) Not less than one-half of the floor area in a primary enclosure used to transport sea otters shall be leakproof and shall contain sufficient crushed ice or ice water to provide each sea otter contained therein with moisture necessary to allow each sea otter to maintain its hair coat by preventing it from drying and to minimize soiling of the hair coat with urine and fecal material. No sea otter in need of veterinary care shall be transported in commerce, unless such transportation is for the purpose of obtaining such care.

(d) Polar bears need not be accompanied by an employee or attendant of the shipper or receiver, unless the period of transportation will exceed 24 hours in duration. During surface transportation, it shall be the responsibility of the carrier to inspect polar bears unaccompanied by an employee or attendant at least every 4 hours to determine whether they need veterinary care and to provide any needed veterinary care as soon as possible. When transported by air, live polar bears unaccompanied by an employee or attendant, shall be inspected by the carrier at least every 4 hours if the animal cargo space is accessible during flight. If the animal cargo space is not accessible during flight, the air carrier shall inspect such live unattended polar bears whenever loaded and unloaded and whenever the animal cargo space is otherwise accessible to determine whether such unattended live animals need veterinary care, and the carrier shall provide any needed veterinary care as soon as possible. No polar bear in need of veterinary care shall be transported in commerce, unless such transportation is for the purpose of obtaining such care.

(e) Wild or otherwise dangerous marine mammals shall not be taken from their primary enclosure except under extreme emergency conditions and then only by their trainer or other person who is capable of handling such mammals safely.

(Secs. 3, 5, 6, 10, 11, 12, 16, 17, 21, 80 Stat. 351, 352, 353, 84 Stat. 1561, 1562, 1563, 1564, 90 Stat. 418, 419, 420, 423; 7 U.S.C 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2144, 2146, 2147, 2151; 7 CFR 2.17, 2.51, 371.2(d))

[44 FR 36874, June 22, 1979, as amended at 49 FR 26686, June 28, 1984]

§ 3.117 Terminal facilities.

Carriers and intermediate handlers shall not commingle marine mammal shipments with inanimate cargo. All animal holding areas of a terminal facility of any carrier or intermediate handler wherein marine mammal shipments are maintained shall be cleaned and sanitized in a manner prescribed in § 3.107 of the standards often enough to prevent an accumulation of debris or excreta, to minimize vermin infestation, and to prevent a disease hazard. An effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained for all animal holding areas. Any animal holding area containing marine mammals shall be provided with fresh air by means of windows, door, vents, or air conditioning and may be ventilated or air circulated by means of fans, blowers, or an air conditioning system so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans and vents or fans or blowers or air conditioning shall be used for any animal holding area containing marine mammals when the air temperature within such animal holding area is 23.9° C. (75° F.) or higher. The air temperature around any marine mammal in any animal holding area shall not be allowed to fall below 7.2° C. (45° F.). The air temperature around any polar bear shall not be allowed to exceed 29.5° C. (85° F.) at any time and no polar bear shall be subjected to surrounding air temperatures which exceed 23.9° C. (75° F.) for more than 4 hours at any time. To ascertain compliance with the provisions of this paragraph, the air temperature around any marine mammal shall be measured and read outside the primary enclosure which contains such animal at a distance not to exceed .91 meters (3 feet) from any one of the external walls of the primary enclosure and on a level parallel to the bottom of such primary enclosure at a point which approximates half the distance between the top and bottom of such primary enclosure.

(Secs. 3, 5, 6, 10, 11, 12, 16, 17, 21, 80 Stat. 351, 352, 353, 84 Stat. 1561, 1562, 1563, 1564, 90 Stat. 418, 419, 420, 423; 7 U.S.C 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2144, 2146, 2147, 2151; 7 CFR 2.17, 2.51, 371.2(d))

[44 FR 36874, June 22, 1979, as amended at 49 FR 26686, June 28, 1984]

§ 3.118 Handling.

(a) Carriers and intermediate handlers shall move marine mammals from the animal holding area of the terminal facility to the primary conveyance and from the primary conveyance to the animal holding area of the terminal facility as expeditiously as possible. Carriers and intermediate handlers holding any marine mammal in an animal holding area of a terminal facility or in transporting any marine mammal from the animal holding area of the terminal facility to the primary conveyance and from the primary conveyance to the animal holding area of the terminal facility, including loading and unloading procedures, shall provide the following:

(1) *Shelter from sunlight.* When sunlight is likely to cause overheating or discomfort, sufficient shade shall be provided to protect the marine mammals from the direct rays of the sun and such marine mammals shall not be subjected to surrounding air temperatures which exceed 29.5° C. (85° F.), and which shall be measured and read in the manner prescribed in § 3.117 of this part, for a period of more than 45 minutes.

(2) *Shelter from cold weather.* Transporting devices shall be covered to provide protection for marine mammals when the outdoor air temperature falls below 10° C. (50° F.) and such marine mammals shall not be subjected to surrounding air temperatures which fall below 7.2° C. (45° F.), and which shall be measured and read in the manner prescribed in § 3.117 of this part, for a period of more than 45 minutes unless such animals are accompanied by a certificate of acclimation to lower temperatures as prescribed in § 3.112(c).

(b) Care shall be exercised to avoid handling of the primary enclosure in such a manner that may cause physical or emotional trauma to the marine mammal contained therein.

(c) Primary enclosures used to transport any marine mammal shall not be tossed, dropped, or needlessly tilted and shall not be stacked in a manner which may reasonably be expected to result in their falling.

(Secs. 3, 5, 6, 10, 11, 12, 16, 17, 21, 80 Stat. 351, 352, 353, 84 Stat. 1561, 1562, 1563, 1564, 90 Stat. 418, 419, 420, 423; 7 U.S.C 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2144, 2146, 2147, 2151; 7 CFR 2.17, 2.51, 371.2(d))

[44 FR 36874, June 22, 1979, as amended at 49 FR 26686, June 28, 1984]

Subpart F—Specifications for the Humane Handling, Care, Treatment, and Transportation of Warmblooded Animals Other Than Dogs, Cats, Rabbits, Hamsters, Guinea Pigs, Nonhuman Primates, and Marine Mammals

AUTHORITY: Secs. 3, 5, 6, 10, 11, 12, 16, 17, 21, 80 Stat. 351, 352, 353, as amended; 7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2142, 2146, 2147, 2151.

SOURCE: 36 FR 24925, Dec. 24, 1971, unless otherwise noted. Redesignated at 44 FR 36874, July 22, 1979.

FACILITIES AND OPERATING STANDARDS

§ 3.125 Facilities, general.

(a) *Structural strength.* The facility must be constructed of such material and of such strength as appropriate for the animals involved. The indoor and outdoor housing facilities shall be structurally sound and shall be maintained in good repair to protect the animals from injury and to contain the animals.

(b) *Water and power.* Reliable and adequate electric power, if required to comply with other provisions of this subpart, and adequate potable water shall be available on the premises.

(c) *Storage.* Supplies of food and bedding shall be stored in facilities which adequately protect such supplies against deterioration, molding, or contamination by vermin. Refrigeration shall be provided for supplies of perishable food.

(d) *Waste disposal.* Provision shall be made for the removal and disposal of animal and food wastes, bedding, dead animals, trash and debris. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, and disease hazards. The disposal facilities and any disposal of animal and food wastes, bedding, dead animals, trash, and debris shall comply with applicable Federal, State, and local laws and regulations relating to pollution control or the protection of the environment.

(e) *Washroom and sinks.* Facilities, such as washrooms, basins, showers, or sinks, shall be provided to maintain cleanliness among animal caretakers.

[36 FR 24925, Dec. 24, 1971. Redesignated at 44 FR 36874, June 22, 1979, and amended at 44 FR 63492, Nov. 2, 1979]

§ 3.126 Facilities, indoor.

(a) *Ambient temperatures.* Temperature in indoor housing facilities shall be sufficiently regulated by heating or cooling to protect the animals from the extremes of temperature, to provide for their health and to prevent their discomfort. The ambient temperature shall not be allowed to fall below nor rise above temperatures compatible with the health and comfort of the animal.

(b) *Ventilation.* Indoor housing facilities shall be adequately ventilated by natural or mechanical means to provide for the health and to prevent discomfort of the animals at all times. Such facilities shall be provided with fresh air either by means of windows, doors, vents, fans, or air-conditioning and shall be ventilated so as to minimize drafts, odors, and moisture condensation.

(c) *Lighting.* Indoor housing facilities shall have ample lighting, by natural or artificial means, or both, of good quality, distribution, and duration as appropriate for the species involved. Such lighting shall be uniformly distributed and of sufficient intensity to permit routine inspection and cleaning. Lighting of primary enclosures shall be designed to protect the animals from excessive illumination.

(d) *Drainage.* A suitable sanitary method shall be provided to eliminate rapidly, excess water from indoor housing facilities. If drains are used, they shall be properly constructed and kept in good repair to avoid foul odors and installed so as to prevent any backup of sewage. The method of drainage shall comply with applicable Federal, State, and local laws and regulations relating to pollution control or the protection of the environment.

§ 3.127 Facilities, outdoor.

(a) *Shelter from sunlight.* When sunlight is likely to cause overheating or discomfort of the animals, sufficient shade by natural or artificial means shall be provided to allow all animals kept outdoors to protect themselves from direct sunlight.

(b) *Shelter from inclement weather.* Natural or artificial shelter appropriate to the local climatic conditions for the species concerned shall be provided for all animals kept outdoors to afford them protection and to prevent discomfort to such animals. Individual animals shall be acclimated before they are exposed to the extremes of the individual climate.

(c) *Drainage.* A suitable method shall be provided to rapidly eliminate excess water. The method of drainage shall comply with applicable Federal, State, and local laws and regulations relating to pollution control or the protection of the environment.

§ 3.128 Space requirements.

Enclosures shall be constructed and maintained so as to provide sufficient space to allow each animal to make normal postural and social adjustments with adequate freedom of movement. Inadequate space may be indicated by evidence of malnutrition, poor condition, debility, stress, or abnormal behavior patterns.

ANIMAL HEALTH AND HUSBANDRY STANDARDS

§ 3.129 Feeding.

(a) The food shall be wholesome, palatable, and free from contamination and of sufficient quantity and nutritive value to maintain all animals in good health. The diet shall be prepared with consideration for the age, species, condition, size, and type of the animal. Animals shall be fed at least once a day except as dictated by hibernation, veterinary treatment, normal fasts, or other professionally accepted practices.

(b) Food, and food receptacles, if used, shall be sufficient in quantity and located so as to be accessible to all animals in the enclosure and shall be placed so as to minimize contamination. Food receptacles shall be kept clean and sanitary at all times. If self-feeders are used, adequate measures shall be taken to prevent molding, contamination, and deterioration or caking of food.

§ 3.130 Watering.

If potable water is not accessible to the animals at all times, it must be provided as often as necessary for the health and comfort of the animal. Frequency of watering shall consider age, species, condition, size, and type of the animal. All water receptacles shall be kept clean and sanitary.

§ 3.131 Sanitation.

(a) *Cleaning of enclosures.* Excreta shall be removed from primary enclosures as often as necessary to prevent contamination of the animals contained therein and to minimize disease hazards and to reduce odors. When enclosures are cleaned by hosing or flushing, adequate measures shall be taken to protect the animals confined in such enclosures from being directly sprayed with the stream of water or wetted involuntarily.

(b) *Sanitation of enclosures.* Subsequent to the presence of an animal with an infectious or transmissible disease, cages, rooms, and hard-surfaced pens or runs shall be sanitized either by washing them with hot water (180 F. at source) and soap or detergent, as in a mechanical washer, or by washing all soiled surfaces with a detergent solution followed by a safe and effective disinfectant, or by cleaning all soiled surfaces with saturated live steam under pressure. Pens or runs using gravel, sand, or dirt, shall be sanitized when necessary as directed by the attending veterinarian.

(c) *Housekeeping.* Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart. Accumulations of trash shall be placed in designated areas and cleared as necessary to protect the health of the animals.

(d) *Pest control.* A safe and effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained.

§ 3.132 Employees.

A sufficient number of adequately trained employees shall be utilized to maintain the professionally acceptable level of husbandry practices set forth in this subpart. Such practices shall be under a supervisor who has a background in animal care.

§ 3.133 Separation.

Animals housed in the same primary enclosure must be compatible. Animals shall not be housed near animals that interfere with their health or cause them discomfort.

§ 3.134 Veterinary care.

(a) Programs of disease prevention and parasite control euthanasia, and adequate veterinary care shall be established and maintained under the supervision of a veterinarian. The pest control program shall be reviewed by the veterinarian for the safe use of materials and methods. Such veterinarian shall be a graduate of an approved college of veterinary medicine.

(b) Animals shall be observed every day by the person in charge of the care of the animals or by someone working under his direct supervision. Sick or diseased, stressed, injured, or lame animals shall be provided with veterinary care or humanely destroyed, unless such action is inconsistent with the research purposes for which the animal was obtained and is being held.

(c)(1) In the case of a research facility, the program of adequate veterinary care shall include the appropriate use of anesthetic, analgesic, or tranquilizing drugs, when such use would be proper in the opinion of the attending veterinarian at the research facility. The use of these three classes of drugs shall be in accordance with the currently accepted veterinary medical practice as cited in appropriate professional journals or reference guides which shall produce in the individual subject animal a high level of tranquilization, anesthesia or analgesia consistent with the protocol or design of the experiment.

(2) It shall be incumbent upon each research facility through its Animal Care Committee and/or attending veterinarian to provide guidelines and consultation to research personnel with respect to the type and amount of tranquilizers, anesthetics, or analgesics recommended as being appropriate for each species of animal used by that institution.

(3) The use of those three classes of drugs shall effectively minimize the pain and discomfort of the animals while under experimentation.

§ 3.135 Handling.

(a) Handling of animals shall be done as expeditiously and carefully in a way so as not to cause unnecessary discomfort, behavioral stress, or physical harm to the animal. Care should be exercised also to avoid harm to the handler.

(b) Animals to which the public is afforded direct contact shall only be displayed for periods of time and under conditions consistent with the animals' health and not leading to their discomfort.

(c) During public display, the animals must be handled so there is minimal risk of harm to the public with sufficient distance allowed between animal acts and the viewing public to assure safety to both the public and the animals. Performing animals shall be allowed a rest period between performances equal to the time for one performance.

TRANSPORTATION STANDARDS

AUTHORITY: Secs. 3, 5, 6, 10, 11, 14, 16, 17, 21; 80 Stat. 353; 84 Stat. 1561, 1562, 1563, 1564; 90 Stat. 418, 419, 420, 423; (7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2144, 2146, 2147, 2151); 37 FR 28464, 28477, 38 FR 19141.

SOURCE: Sections 3.136 through 3.142 appear at 42 FR 31569, June 21, 1977, unless otherwise noted. Redesignated at 44 FR 36874, July 22, 1979.

§ 3.136 Consignments to carriers and intermediate handlers.

(a) Carriers and intermediate handlers shall not accept any live animals presented by any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or any State or local government for shipment, in commerce, more than 4 hours prior to the scheduled departure of the primary conveyance on which it is to be transported: *Provided, however,* That the carrier or intermediate handler and any dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or any State or local government may mutually agree to extend the time of acceptance to not more than 6 hours if specific prior scheduling of the animal shipment to destination has been made.

(b) Any carrier or intermediate handler shall only accept for transportation or transport, in commerce, any live animal in a primary enclosure which conforms to the requirements set forth in § 3.137 of the standards: *Provided, however,* That any carrier or intermediate handler may accept for transportation or transport, in commerce, any live animal consigned by any department, agency, or instrumentality of the United States having laboratory animal facilities or exhibiting animals or any licensed or registered dealer, research facility, exhibitor, or operator of an auction sale if the consignor furnishes to the carrier or intermediate handler a certificate, signed by the consignor, stating that the primary enclosure complies with § 3.137 of the standards, unless such primary enclosure is obviously defective or damaged and it is apparent that it cannot reasonably be expected to contain the live animal without causing suffering or injury to such live animal. A copy of such certificate shall accompany the shipment to destination. The certificate shall include at least the following information:

(1) Name and address of the consignor;

(2) The number of animals in the primary enclosure(s);

(3) A certifying statement (e.g., "I hereby certify that the —— (number) primary enclosure(s) which are used to transport the animal(s) in this shipment complies (comply) with USDA standards for primary enclosures (9 CFR Part 3)."); and

(4) The signature of the consignor, and date.

(c) Carriers or intermediate handlers whose facilities fail to meet the minimum temperature allowed by the standards may accept for transportation or transport, in commerce, any live animal consigned by any department, agency, or instrumentality of the United States or of any State or local government, or by any person (including any licensee or registrant under the Act, as well as any private individual) if the consignor furnishes to the carrier or intermediate handler a certificate executed by a veterinarian accredited by this Department pursuant to Part 160 of this title on a specified date which shall not be more than 10 days prior to delivery of such animal for transportation in commerce, stating that such live animal is acclimated to air temperatures lower than those prescribed in §§ 3.141 and 3.142. A copy of such certificate shall accompany the shipment to destination. The certificate shall include at least the following information:

(1) Name and address of the consignor;

(2) The number of animals in the shipment;

(3) A certifying statement (e.g., "I hereby certify that the animal(s) in this shipment is (are), to the best of my knowledge, acclimated to air temperatures lower than 7.2° C. (45° F.)"); and

(4) The signature of the USDA accredited veterinarian, assigned accreditation number, and date.

(d) Carriers and intermediate handlers shall attempt to notify the consignee at least once in every 6 hour period following the arrival of any live animals at the animal holding area of the terminal cargo facility. The time, date, and method of each attempted notification and the final notification to the consignee and the name of the person notifying the consignee shall be recorded on the copy of the shipping document retained by the carrier or intermediate handler and on a copy of the shipping document accompanying the animal shipment.

[42 FR 31569, June 21, 1977, as amended at 43 FR 21166, May 16, 1978. Redesignated at

44 FR 36874, July 22, 1979, and amended at 44 FR 63493, Nov. 2, 1979]

§ 3.137 Primary enclosures used to transport live animals.

No dealer, research facility, exhibitor, or operator of an auction sale shall offer for transportation or transport, in commerce, any live animal in a primary enclosure which does not conform to the following requirements:

(a) Primary enclosures, such as compartments, transport cages, cartons, or crates, used to transport live animals shall be constructed in such a manner that (1) the structural strength of the enclosure shall be sufficient to contain the live animals and to withstand the normal rigors of transportation; (2) the interior of the enclosure shall be free from any protrusions that could be injurious to the live animals contained therein; (3) the opernings of such enclosures are easily accessible at all times for emergency removal of the live animals; (4) except as provided in paragraph (g) of this section, there are ventilation openings located on two opposite walls of the primary enclosure and the ventilation openings on each such wall shall be at least 16 percent of the total surface area of each such wall, or there are ventilation openings located on all four walls of the primary enclosure and the ventilation openings on each such wall shall be at least 8 percent of the total surface area of each such wall: *Provided, however,* That at least one-third of the total minimum area required for ventilation of the primary enclosure shall be located on the lower one-half of the primary enclosure and at least one-third of the total minimum area required for ventilation of the primary enclosure shall be located on the upper one-half of the primary enclosure; (5) except as provided in paragraph (g) of this section, projecting rims or other devices shall be on the exterior of the outside walls with any ventilation openings to prevent obstruction of the ventilation openings and to provide a minimum air circulation space of 1.9 centimeters (.75 inch) between the primary enclosure and any adjacent cargo or conveyance wall; and (6) except as provided in paragraph (g) of this section, adequate handholds or other devices for lifting shall be provided on the exterior of the primary enclosure to enable the primary enclosure to be lifted without tilting and to ensure that the person handling the primary enclosure will not be in contact with the animal.

(b) Live animals transported in the same primary enclosure shall be of the same species and maintained in compatible groups. Live animals that have not reached puberty shall not be transported in the same primary enclosure with adult animals other than their dams. Socially dependent animals (e.g., sibling, dam, and other members of a family group) must be allowed visual and olfactory contact. Any female animal in season (estrus) shall not be transported in the same primary enclosure with any male animal.

(c) Primary enclosures used to transport live animals shall be large enough to ensure that each animal contained therein has sufficient space to turn about freely and to make normal postural adjustments: *Provided, however,* That certain species may be restricted in their movements according to professionally acceptable standards when such freedom of movement would constitute a danger to the animals, their handlers, or other persons.

(d) Primary enclosures used to transport live animals as provided in this section shall have solid bottoms to prevent leakage in shipment and still be cleaned and sanitized in a manner prescribed in § 3.131 of the standards, if previously used. Such primary enclosures shall contain clean litter of a suitable absorbant material, which is safe and nontoxic to the live animals contained therein, in sufficient quantity to absorb and cover excreta, unless the animals are on wire or other nonsolid floors.

(e) Primary enclosures used to transport live animals, except where such primary enclosures are permanently affixed in the animal cargo space of the primary conveyance, shall be clearly marked on top and on one or more sides with the words "Live Animal" or "Wild Animal", whichever is appropriate, in letters not less than 2.5 centimeters (1 inch) in height, and with arrows or other markings to indicate the correct upright position of the container.

(f) Documents accompanying the shipment shall be attached in an easily accessible manner to the outside of a primary enclosure which is part of such shipment.

(g) When a primary enclosure is permanently affixed within the animal cargo space of the primary conveyance so that the front opening is the only source of ventilation for such primary enclosure, the front opening shall open directly to the outside or to an unobstructed aisle or passageway within the primary conveyance. Such front ventilation opening shall be at least 90 percent of the total surface area of the front wall of the primary enclosure and covered with bars, wire mesh or smooth expanded metal.

[42 FR 31569, June 21, 1977, as amended at 43 FR 21166, May 16, 1978. Redesignated at 44 FR 36874, July 22, 1979]

§ 3.138 Primary conveyances (motor vehicle, rail, air, and marine).

(a) The animal cargo space of primary conveyances used in transporting live animals shall be designed and constructed to protect the health, and ensure the safety and comfort of the live animals contained therein at all times.

(b) The animal cargo space shall be constructed and maintained in a manner to prevent the ingress of engine exhaust fumes and gases from the primary conveyance during transportation in commerce.

(c) No live animal shall be placed in an animal cargo space that does not have a supply of air sufficient for normal breathing for each live animal contained therein, and the primary enclosures shall be positioned in the animal cargo space in such a manner that each live animal has access to sufficient air for normal breathing.

(d) Primary enclosures shall be positioned in the primary conveyance in such a manner that in an emergency the live animals can be removed from the primary conveyance as soon as possible.

(e) The interior of the animal cargo space shall be kept clean.

(f) Live animals shall not be transported with any material, substance (e.g., dry ice) or device which may reasonably be expected to be injurious to the health and well-being of the animals unless proper precaution is taken to prevent such injury.

§ 3.139 Food and water requirements.

(a) All live animals shall be offered potable water within 4 hours prior to being transported in commerce. Dealers, exhibitors, research facilities and operators of auction sales shall provide potable water to all live animals transported in their own primary conveyance at least every 12 hours after such transportation is initiated, and carriers and intermediate handlers shall provide potable water to all live animals at least every 12 hours after acceptance for transportation in commerce: *Provided, however,* That except as directed by hibernation, veterinary treatment or other professionally accepted practices, those live animals which, by common accepted practices, require watering more frequently shall be so watered.

(b) Each live animal shall be fed at least once in each 24 hour period, except as directed by hibernation, veterinary treatment, normal fasts, or other professionally accepted practices. Those live animals which, by common accepted practice, require feeding more frequently shall be so fed.

(c) A sufficient quantity of food and water shall accompany the live animal to provide food and water for such animals for a period of at least 24 hours, except as directed by hibernation, veterinary treatment, normal fasts, and other professionally accepted practices.

(d) Any dealer, research facility, exhibitor or operator of an auction sale offering any live animal to any carrier or intermediate handler for transportation in commerce shall affix to the outside of the primary enclosure used for transporting such live animal, written instructions concerning the food and water requirements of such animal while being so transported.

(e) No carrier or intermediate handler shall accept any live animals for transportation in commerce unless written instructions concerning the food and water requirements of such animal while being so transported is affixed to the outside of its primary enclosure.

§ 3.140 Care in transit.

(a) During suface transportation, it shall be the responsibility of the driver or other employee to visually observe the live animals as frequently as circumstances may dictate, but not less than once every 4 hours, to assure that they are receiving sufficient air for normal breathing, their ambient temperatures are within the prescribed limits, all other applicable standards are being complied with and to determine whether any of the live animals are in obvious physical distress and to provide any needed veterinary care as soon as possible. When transported by air, live animals shall be visually observed by the carrier as frequently as circumstances may dictate, but not less than once every 4 hours, if the animal cargo space is accessible during flight. If the animal cargo space is not accessible during flight, the carrier shall visually observe the live animals whenever loaded and unloaded and whenever the animal cargo space is otherwise accessible to assure that they are receiving sufficient air for normal breathing, their ambient temperatures are within the prescribed limits, all other applicable standards are being complied with and to determine whether any such live animals are in obvious physical distress. The carrier shall provide any needed veterinary care as soon as possible. No animal in obvious physical distress shall be transported in commerce.

(b) Wild or otherwise dangerous animals shall not be taken from their primary enclosure except under extreme emergency conditions: *Provided, however,* That a temporary primary enclosure may be used, if available, and such temporary primary enclosure is structurally strong enough to prevent the escape of the animal. During the course of transportation, in commerce, live animals shall not be removed from their primary enclosures unless placed in other primary enclosures or facilities conforming to the requirements provided in this subpart.

§ 3.141 Terminal facilities.

Carriers and intermediate handlers shall not commingle live animal shipments with inanimate cargo. All animal holding areas of a terminal facility of any carrier or intermediate handler wherein live animal shipments are maintained shall be cleaned and sanitized in a manner prescribed in § 3.141 of the standards often enough to prevent an accumulation of debris or excreta, to minimize vermin infestation and to prevent a disease hazard. An effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained for all animal holding areas. Any animal holding area containing live animals shall be provided with fresh air by means of windows, doors vents, or air conditioning and may be ventilated or air circulated by means of fans, blowers, or an air conditioning system so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans and vents or fans or blowers or air conditioning shall be used for any animal holding area containing live animals when the air temperature within such animal holding area is 23.9°C. (75.°F.) or higher. The air temperature around any live animal in any animal holding area shall not be allowed to fall below 7.2°C. (45°F.) nor be allowed to exceed 29.5°C. (85°F.) at any time: *Provided, however,* That no live animal shall be subjected to surrounding air temperatures which exceed 23.9°C. (75°F.) for more than 4 hours at any time. To ascertain compliance with the provisions of this paragraph, the air temperature around any live animal shall be measured and read outside the primary enclosure which contains such animal at a distance not to exceed .91 meters (3 feet) from any one of the external walls of the primary enclosure and on a level parallel to the bottom of such primary enclosure at a point which approximates half the distance between the top and bottom of such primary enclosure.

[43 FR 56217, Dec. 1, 1978. Redesignated at 44 FR 36874, July 22, 1979]

§ 3.142 Handling.

(a) Carriers and intermediate handlers shall move live animals from the animal holding area of the terminal facility to the primary conveyance and from the primary conveyance to the animal holding area of the terminal facility as expeditiously as possible. Carriers and intermediate handlers holding any live animal in an animal holding area of a terminal facility or in transporting any live animal from the animal holding area of the terminal facility to the primary conveyance and from the primary conveyance to the animal holding area of the terminal facility, including loading and unloading procedures, shall provide the following:

(1) *Shelter from sunlight.* When sunlight is likely to cause overheating or discomfort, sufficient shade shall be provided to protect the live animals from the direct rays of the sun and such live animals shall not be subjected to surrounding air temperatures which exceed 29.5°C. (85°F.), and which shall be measured and read in the manner prescribed in § 3.141 of this part, for a period of more than 45 minutes.

(2) *Shelter from rain or snow.* Live animals shall be provided protection to allow them to remain dry during rain or snow.

(3) *Shelter from cold weather.* Transporting devices shall be covered to provide protection for live animals when the outdoor air temperature falls below 10°C. (50°F.) and such live animals shall not be subjected to surrounding air temperatures which fall below 7.2°C. (45°F.), and which shall be measured and read in the manner prescribed in § 3.141 of this Part, for a period of more than 45 minutes unless such animals are accompanied by a certificate of acclimation to lower temperatures as prescribed in § 3.136(c).

(b) Care shall be exercised to avoid handling of the primary enclosure in such a manner that may cause physical or emotional trauma to the live animal contained therein.

(c) Primary enclosures used to transport any live animal shall not be tossed, dropped, or needlessly tilted and shall not be stacked in a manner which may reasonably be expected to result in their falling.

(Secs. 3, 5, 6, 10, 11, 12, 13, 14, 16, 17, 21, 80 Stat. 351, 352, 353, 84 Stat. 1561, 1562, 1563, 1564, 90 Stat. 418, 419, 420, 423 (7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2144, 2146, 2147, 2151); 37 FR 28464, 28477, 38 FR 19141)

[43 FR 21167, May 16, 1978, as amended at 43 FR 56217, Dec. 1, 1978. Redesignated at 44 FR 36874, July 22, 1979]

PART 4—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE ANIMAL WELFARE ACT

Subpart A—General

Sec.

4.1 Scope and applicability of rules of practice.

Subpart B—Supplemental Rules of Practice

4.10 Summary action.
4.11 Stipulations.

AUTHORITY: 80 Stat. 353; 7 U.S.C. 2151.

SOURCE: 42 FR 10959, Feb. 25, 1977, unless otherwise noted.

Subpart A—General

§ 4.1 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the department of Agriculture promulgated in Subpart H of Part 1, Subtitle A, Title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings under section 19 of the Animal Welfare Act (7 U.S.C. 2149). In addition, the Supplemental Rules of Practice set forth in Subpart B of this part shall be applicable to such proceedings.

Subpart B—Supplemental Rules of Practice

§ 4.10 Summary action.

(a) In any situation where the Administrator has reason to believe that any person licensed under the Act has violated or is violating any provision of the Act, or the regulations or standards issued thereunder, and he deems it warranted under the circumstances, the Administrator may suspend such person's license temporarily, for a period not to exceed 21 days, effective, except as provided in § 4.10(b), upon written notification given to such person of the suspension of his license pursuant to § 1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)).

(b) In any case of actual or threatened physical harm to animals in violation of the Act, or the regulations or standards issued thereunder, by a person licensed under the Act, the Administrator may suspend such person's license temporarily, for a period not to exceed 21 days, effective upon oral or written notification, whichever is earlier. In the event of oral notification, a written confirmation thereof shall be given to such person pursuant to § 1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)) as promptly as circumstances permit.

(c) The temporary suspension of a license shall be in addition to any sanction which may be imposed against said person by the Secretary pursuant to the Act after notice and opportunity for hearing.

§ 4.11 Stipulations.

(a) At any time prior to the issuance of a complaint seeking a civil penalty under the Act, the Administrator, in his discretion, may enter into a stipulation with any person in which:

(1) The Administrator gives notice of an apparent violation of the Act, or the regulations or standards issued thereunder, by such person and affords such person an opportunity for a hearing regarding the matter as provided by the Act;

(2) Such person expressly waives hearing and agrees to pay a specified penalty within a designated time; and

(3) The Administrator agrees to accept the specified penalty in settlement of the particular matter involved if it is paid within the designated time.

(b) If the specified penalty is not paid within the time designated in such a stipulation, the amount of the stipulated penalty shall not be relevant in any respect to the penalty which may be assessed after issuance of a complaint.

PART 11—HORSE PROTECTION REGULATIONS

Sec.

11.1 Definitions.
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11.4 Inspection and detention of horses.
11.5 Access to premises and records.
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11.22 Inspection of records.
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11.41 Reporting required of horse industry organizations or associations.

AUTHORITY: Secs. 4, 6, and 9; 84 Stat. 1404; 90 Stat. 916 and 918; (15 U.S.C. 1823, 1825, and 1828); 29 FR 16210; 36 FR 20707.

SOURCE: 44 FR 25179, Apr. 27, 1979, unless otherwise noted.

§ 11.1 Definitions.

For the purpose of this part, unless the context otherwise requires, the following terms shall have the meanings assigned to them in this section. The singular form shall also impart the plural and the masculine form shall also impart the feminine. Words of art undefined in the following paragraphs shall have the meaning attributed to them by trade usage or general usage as reflected by definition in a standard dictionary, such as "Webster's."

(a) "Act" means the Horse Protection Act of 1970 (Pub. L. 91-540) as amended by the Horse Protection Act Amendments of 1976 (Pub. L. 94-360), 15 U.S.C. 1821 *et seq.*, and any legislation amendatory thereof.

(b) "Department" means the United States Department of Agriculture.

(c) "Secretary" means the Secretary of Agriculture or anyone who has heretofore or may hereafter be delegated authority to act in his stead.

(d) "Administrator" means the Administrator of the Animal and Plant Health Inspection Service or any other official of the Department to whom authority has heretofore been delegated or to whom authority may hereafter be delegated to act in his stead.

(e) "Deputy Administrator" means the Deputy Administrator for Veterinary Services or any other official of Veterinary Services to whom authority has heretofore been delegated or to whom authority may hereafter be delegated, to act in his stead.

(f) "Veterinary Services" means the office of the Animal and Plant Health Inspection Service to which responsibility is assigned for the administration of the Act.

(g) "Veterinarian in Charge" means the Veterinary Services veterinarian who is assigned by the Deputy Administrator to supervise and perform official duties of Veterinary Services under the Act in a specified State or States.[1]

(h) "Veterinary Services Show Veterinarian" means the Veterinary Services Doctor of Veterinary Medicine, responsible for the immediate supervision and conduct of the Department's activities under the Act at any horse show, horse exhibition, horse sale or horse auction.

(i) "Veterinary Services representative" means any employee of Veterinary Services, or any officer or employee of any State agency who is authorized by the Deputy Administrator to perform inspections or any other functions authorized by the Act, including the inspection of the records of any horse show, horse exhibition, horse sale or horse auction.

(j) "State" means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

(k) "Person" means any individual, corporation, company, association, firm, partnership, society, organization, joint stock company, or other legal entity.

(l) "Horse" means any member of the species *Equus caballus.*

(m) "Horse Show" means a public display of any horses, in competition, except events where speed is the prime factor, rodeo events, parades, or trail rides.

(n) "Horse Exhibition" means a public display of any horses, singly or in groups, but not in competition, except events where speed is the prime factor, rodeo events, parades, or trail rides.

(o) "Horse Sale or Horse Auction" means any event, public or private, at which horses are sold or auctioned, regardless of whether or not said horses are exhibited prior to or during the sale or auction.

(p) "Action Device" means any boot, collar, chain, roller, or other device which encircles or is placed upon the lower extremity of the leg of a horse in such a manner that it can either rotate around the leg, or slide up and down the leg so as to cause friction, or which can strike the hoof, coronet band or fetlock joint.

(q) "Inspection" means the examination of any horse and any records pertaining to any horse by use of whatever means are deemed appropriate and necessary for the purpose of determining compliance with the Act and regulations. Such inspection may include, but is not limited to, visual examination of a horse and records, actual physical examination of a horse including touching, rubbing, palpating and observation of vital signs, and the use of any diagnostic device or instrument, and may require the removal of any shoe, pad, action device, or any other equipment, substance or paraphernalia from the horse when deemed necessary by the person conducting such inspection.

(r) "Sponsoring Organization" means any person under whose immediate auspices and responsibility a horse show, horse exhibition, horse sale, or horse auction is conducted.

(s) "Show Manager" means the person who has been delegated primary authority by a sponsoring organization for managing a horse show, horse exhibition, horse sale or horse auction.

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[1] Information as to the name and address of the Veterinarian in Charge for the State or States concerned can be obtained by writing to the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Hyattsville, MD 20782.

(t) "Management" means any person or persons who organize, exercise control over, or administer or are responsible for organizing, directing, or administering any horse show, horse exhibition, horse sale or horse auction and specifically includes, but is not limited to, the sponsoring organization and show manager.

(u) "Exhibitor" means (1) any person who enters any horse, any person who allows his horse to be entered, or any person who directs or allows any horse in his custody or under his direction, control or supervision to be entered in any horse show or horse exhibition; (2) any person who shows or exhibits any horse, any person who allows his horse to be shown or exhibited, or any person who directs or allows any horse in his custody or under his direction, control, or supervision to be shown or exhibited in any horse show or horse exhibition; (3) any person who enters or presents any horse for sale or auction, any person who allows his horse to be entered or presented for sale or auction, or any person who allows any horse in his custody or under his direction, control, or supervision to be entered or presented for sale or auction in any horse sale or horse auction; or (4) any person who sells or auctions any horse, any person who allows his horse to be sold or auctioned, or any person who directs or allows any horse in his custody or under his direction, control, or supervision to be sold or auctioned.

(v) "Designated Qualified Person" or "DQP" means a person meeting the requirements specified in § 11.7 of this part who has been licensed as a DQP by a horse industry organization or association having a DQP program certified by the Department and who may be appointed and delegated authority by the management of any horse show, horse exhibition, horse sale or horse auction under Section 4 of the Act to detect or diagnose horses which are sore or to otherwise inspect horses and any records pertaining to such horses for the purposes of enforcing the Act.

(w) "Horse Industry Organization or Association" means an organized group of people, having a formal structure, who are engaged in the promotion of horses through the showing, exhibiting, sale, auction, registry, or any activity which contributes to the advancement of the horse.

(x) "Lubricant" means mineral oil, glycerine or petrolatum, or mixtures exclusively thereof, that is applied to the limbs of a horse solely for protective and lubricating purposes while the horse is being shown or exhibited at a horse show, horse exhibition, horse sale or horse auction.

(y) "Sore" when used to describe a horse means:

(1) An irritating or blistering agent has been applied, internally or externally by a person to any limb of a horse,

(2) Any burn, cut, or laceration has been inflicted by a person on any limb of a horse,

(3) Any tack, nail, screw, or chemical agent has been injected by a person into or used by a person on any limb of a horse, or

(4) Any other substance or device has been used by a person on any limb of a horse or a person has engaged in a practice involving a horse, and, as a result of such application, infliction, injection, use, or practice, such horse suffers, or can reasonably be expected to suffer, physical pain or distress, inflammation, or lameness when walking, trotting, or otherwise moving, except that such term does not include such an application, infliction, injection, use, or practice in connection with the therapeutic treatment of a horse by or under the supervision of a person licensed to practice veterinary medicine in the State in which such treatment was given.

[44 FR 1561, Jan. 5, 1979]

§ 11.2 Prohibitions concerning exhibitors.

(a) *General prohibitions.* Notwithstanding the provisions of paragraph (b) of this section, no chain, boot, roller, collar, action device, nor any other device, method, practice, or substance shall be used with respect to any horse at any horse show, horse exhibition, or horse sale or auction if such use causes or can reasonably be expected to cause such horse to be sore.

(b) *Specific prohibitions.* The use of any of the following devices, equipment, or practices on any horse at any horse show, horse exhibition, or horse sale or auction is prohibited:

(1) All beads, bangles, rollers, and similar devices, with the exception of rollers made of lignum vitae (hardwood), aluminum, or stainless steel, with individual rollers being of uniform size, weight and configuration, provided each such device may not weigh more than 14 ounces, including the weight of the fastener.

(2) Chains weighing in excess of 8 ounces each including the weight of the fastener on 2-year-old horses and chains weighing in excess of 10 ounces each including the weight of the fastener on horses 3 years old or older.

(3) Chains with links that are not of uniform size, weight and configuration; and, chains that have twisted links or double links.

(4) Chains that have drop links on any horse that is being ridden, worked on a lead, or otherwise worked out or moved about.

(5) More than one action device on any one limb of a horse.

(6) Chains or lignum vitae, stainless steel, or aluminum rollers which are not smooth and free of protrusions, projections, rust, corrosion, or rough or sharp edges.

(7) Boots, collars, or any other device, with protrusions or swellings, or rigid, rough, or sharp edges, seams or any other abrasive or abusive surface that may contact a horse's leg.

(8) Pads or any other devices on yearling horses (horses up to 2 years old) that elevate or change the angle of such horses' hooves in excess of 1 inch at the heel.

(9) Any weight on yearling horses, except a keg or other similar, conventional type horseshoe, and any horseshoe on yearling horses that weighs in excess of 16 ounces.

(10) Toe length that does not exceed the height of the heel by 1 inch or more. The length of the toe shall be measured from the coronet band, at the center of the front pastern along the front of the hoof wall, to the ground. The heel shall be measured from the coronet band, at the most lateral portion of the rear pastern, at a 90 degree angle to the ground, not including normal caulks at the rear of a horseshoe that do not exceed ¾ inch in length. That portion of caulk at the rear of a horseshoe in excess of ¾ of an inch shall be added to the height of the heel in determining the heel-toe ratio.

(11) Artificial extension of the toe length, whether accomplished with horseshoes, pads, acrylics or any other material or combinations thereof, unless such extension assumes the normal angle of the hoof wall and pastern and is therapeutically necessary to repair a broken hoof.

(12) Single or double rocker-bars on the bottom surface of horseshoes which extend more than 1½ inches back from the point of the toe, or which would cause, or could reasonably be expected to cause, an unsteadiness of stance in the horse with resulting muscle and tendon strain due to the horse's weight and balance being focused upon a small fulcrum point.[2]

(13) Metal hoof bands, such as used to anchor or strengthen pads and shoes, placed less than ½ inch below the coronet band.

(14) Metal hoof bands that can be easily and quickly loosened or tightened by hand, by means such as, but not limited to, a wing-nut or similar fastener.

(15) Any action device or any other device that strikes the coronet band of the foot of a horse except for soft rubber or soft leather bell boots that are used as protective devices.

(16) Shoeing a horse, or trimming a horse's hoof in a manner that will cause such horse to suffer, or can reasonably be expected to cause such horse to suffer pain or distress, in-

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[2] This prohibition is not intended to disallow corrective devices, such as Memphis bars which consist of a metal bar(s) crossing from the ground surface of one side of the horseshoe to the ground surface of the other side of the horseshoe, and the purpose of which is to correct a lameness or pathological condition of the foot: *Provided,* That such metal bar(s) do not act as a single fulcrum point so as to affect the balance of the horse.

flammation, or lameness when walking, trotting, or otherwise moving.

(17) Lead or other weights attached to the outside of the hoof wall, the pad, or on the outside surface of the horseshoe.

(c) *Substances.* All substances are prohibited on the extremities above the hoof of any Tennessee Walking Horse or racking horse while being shown, exhibited, or offered for sale at any horse show, horse exhibition, or horse sale or auction, except lubricants such as glycerine, petrolatum, and mineral oil, or mixtures thereof: *Provided,* That:

(1) The horse show, horse exhibition, or horse sale or auction management agrees to furnish all such lubricants and to maintain control over them when used at the horse show, horse exhibition, or horse sale or auction.

(2) Any such lubricants shall be applied only after the horse has been inspected by management or by a DQP and shall only be applied under the supervision of the horse show, horse exhibition, or horse sale, or auction management.

(3) Horse show, horse exhibition, or horse sale or auction management makes such lubricants available to Department personnel for inspection and sampling as they deem necessary.

(d) *Competition restrictions—2 Year-Old Horses.* Horse show or horse exhibition workouts or performances of 2-year-old Tennessee Walking Horses and racking horses and working exhibitions of 2-year-old Tennessee Walking Horses and racking horses (horses eligible to be shown or exhibited in 2-year-old classes) at horse sales or horse auctions that exceed a total of 10 minutes continuous workout or performance without a minimum 5-minute rest period between the first such 10-minute period and the second such 10-minute period, and, more than two such 10-minute periods per performance, class, or workout are prohibited.

(e) *Information requirements—horse related.* Failing to provide information or providing any false or misleading information required by the Act or regulations or requested by Department representatives, by any person that owns, trains, shows, exhibits, or sells or has custody of, or direction or control over any horse shown, exhibited, sold, or auctioned or entered for the purpose of being shown, exhibited, sold, or auctioned at any horse show, horse exhibition, or horse sale or auction is prohibited. Such information shall include, but is not limited to: Information concerning the registered name, markings, sex, age, and legal ownership of the horse; the name and address of the horse's training and/or stabling facilities; the name and address of the owner, trainer, rider, any other exhibitor, or other legal entity bearing responsibility for the horse; the class in which the horse is entered or shown; the exhibitor identification number; and, any other information reasonably related to the identification, ownership, control, direction, or supervision of any such horse.

§ 11.3 Scar rule.

Starting with the 1979 show season,[3] the scar rule shall apply to all 3-year-old horses[4] during the 1979 season; 4-year-old horses during the 1980 season; 5-year-old horses during the 1981 season, etc. Any horse which is older than a 3-year-old during the 1979 show season shall be unaffected by this rule. Horses subject to this rule which do not meet the following scar rule criteria shall be considered to be "sore" and are subject to all prohibitions of § 5 of the Act. The scar rule criteria are as follows:

(a) The anterior and anterior-lateral surfaces of the fore pasterns (extensor surface) must be free of bilateral granulomas,[5] other bilateral pathological evidence of inflammation, and, other bilateral evidence of abuse indicative of soring including, but not limited to, excessive loss of hair.

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[3] Since horse shows throughout the country occur during most months of the year, the show season shall entail the complete calendar year.

[4] Horses which are eligible to compete in 3-year-old classes. Four-year-old horses would be eligible to compete in 4-year-old classes, etc.

[5] Granuloma is defined as any one of a rather large group of fairly distinctive focal lesions that are formed as a result of inflammatory reactions caused by biological, chemical, or physical agents.

(b) The posterior surfaces of the pasterns (flexor surface), including the sulcus or "pocket" may show bilateral areas of uniformly thickened epithelial tissue if such areas are free of proliferating granuloma tissue, irritation, moisture, edema, or other evidence of inflammation.

§ 11.4 Inspection and detention of horses.

For the purpose of effective enforcement of the Act:

(a) Each horse owner, exhibitor, trainer, or other person having custody of, or responsibility for, any horse at any horse show, horse exhibition, or horse sale or auction, shall allow any Veterinary Services representative to reasonably inspect such horse at all reasonable times and places the Veterinary Services representative may designate. Such inspections may be required of any horse which is stabled, loaded on a trailer, being prepared for show, exhibition, or sale or auction, being exercised or otherwise on the grounds of, or present at, any horse show, horse exhibition, or horse sale or auction, whether or not such horse has or has not been shown, exhibited, or sold or auctioned, or has or has not been entered for the purpose of being shown or exhibited or offered for sale or auction at any such horse show, horse exhibition, or horse sale or auction. Veterinary Services representatives will not generally or routinely delay or interrupt actual individual classes or performances at horse shows, horse exhibitions, or horse sales or auctions for the purpose of examining horses, but they may do so in extraordinary situations, such as but not limited to, lack of proper facilities for inspection, refusal of management to cooperate with Department inspection efforts, reason to believe that failure to immediately perform inspection may result in the loss, removal, or masking of any evidence of a violation of the Act or the regulations, or a request by management that such inspections be performed by a Veterinary Services representative.

(b) When any Veterinary Services representative notifies the owner, exhibitor, trainer, or other person having custody of or responsibility for a horse at any horse show, horse exhibition, or horse sale or auction that Veterinary Services desires to inspect such horse, it shall not be moved from the horse show, horse exhibition, or horse sale or auction until such inspection has been completed and the horse has been released by a Veterinary Services representative.

(c) For the purpose of examination, testing, or taking of evidence, Veterinary Services representatives may detain for a period not to exceed 24 hours any horse, at any horse show, horse exhibition, or horse sale or auction, which is sore or which a Veterinary Services veterinarian has probable cause to believe is sore. Such detained horse may be marked for identification and any such identifying markings shall not be removed by any person other than a Veterinary Services representative.

(d) Detained horses shall be kept under the supervision of a Veterinary Services representative or secured under an official USDA seal or seals in a horse stall, horse trailer, or other facility to which access shall be limited. It shall be the policy of Veterinary Services to have at least one representative present in the immediate detention area when a horse is being held in detention. The official USDA seal or seals may not be broken or removed by any person other than a Veterinary Services representative, unless:

(1) The life or well-being of the detained horse is immediately endangered by fire, flood, windstorm, or other dire circumstances that are beyond human control.

(2) The detained horse is in need of such immediate veterinary attention that its life may be in peril before a Veterinary Services representative can be located.

(3) The horse has been detained for a maximum 24-hour detention period, and a Veterinary Services representative is not available to release the horse.

(e) The owner, exhibitor, trainer, or other person having custody of or responsibility for any horse detained by

Veterinary Services for further examination, testing, or the taking of evidence shall be allowed to feed, water, and provide other normal custodial and maintenance care, such as walking, grooming, etc., for such detained horse: *Provided,* That:

(1) Such feeding, watering, and other normal custodial and maintenance care of the detained horse is rendered under the direct supervision of a Veterinary Services representative.

(2) Any non-emergency veterinary care of the detained horse requiring the use, application, or injection of any drugs or other medication for therapeutic or other purposes is rendered by a Doctor of Veterinary Medicine in the presence of a Veterinary Services representative and, the indentity and dosage of the drug or other medication used, applied, or injected and its purpose is furnished in writing to the Veterinary Services representative prior to such use, application, or injection by the Doctor of Veterinary Medicine attending the horse. The use, application, or injection of such drug or other medication must be approved by the Veterinary Services Show Veterinarian or his appointed representative.

(f) It shall be the policy of Veterinary Services to inform the owner, trainer, exhibitor, or other person having immediate custody of or responsibility for any horse allegedly found to be in violation of the Act or the regulations of such alleged violation or violations before the horse is released by a Veterinary Services representative.

(g) The owner, trainer, exhibitor, or other person having immediate custody of or responsibility for any horse or horses that a Veterinary Services representative determines shall be detained for examination, testing, or taking of evidence pursuant to paragraph (e) of this section shall be informed after such determination is made and shall allow said horse to be immediately put under the supervisory custody of Veterinary Services or secured under official USDA seal as provided in paragraph (d) of this section until the completion of such examination, testing, or gathering of evidence, or until the 24-hour detention period expires.

(h) The owner, trainer, exhibitor, or other person having custody of or responsibility for any horse allegedly found to be in violation of the Act or regulations, and who has been notified of such alleged violation by a Veterinary Services representative as stated in paragraph (f) of this section, may request reexamination and testing of said horse within a 24-hour period: *Provided,* That:

(1) Such request is made to the Veterinary Services Show Veterinarian immediately after the horse has been examined by Veterinary Services representatives and before such horse has been removed from the Veterinary Services inspection facilities; and

(2) The Veterinary Services Show Veterinarian determines that sufficient cause for reexamination and testing exists; and

(3) The horse is maintained under Veterinary Services supervisory custody as prescribed in paragraph (d) of this section until such reexamination and testing has been completed.

(i) The owner, exhibitor, trainer, or other person having custody of, or responsibility for any horse being inspected shall render such assistance as the Veterinary Services representative may request for purposes of such inspection.

§ 11.5 Access to premises and records.

Requirements regarding access to premises for inspection of horses and records are as follows:

(a) *Management.* (1) The management of any horse show, horse exhibition, or horse sale or auction shall, without fee, charge, assessment, or other compensation, provide Veterinary Services representatives with unlimited access to the grandstands, sale ring, barns, stables, grounds, offices, and all other areas of any horse show, horse exhibition, or horse sale or auction, including any adjacent areas under their direction, control, or supervision for the purpose of inspecting any horses, or any records required to be kept by regulation or otherwise maintained.

(2) The management of any horse show, horse exhibition, or horse sale or auction shall, without fee, charge, assessment, or other compensation, provide Veterinary Services representatives with an adequate, safe, and accessible area for the visual inspection and observation of horses while such horses are competitively or otherwise performing at any horse show or horse exhibition, or while such horses are being sold or auctioned or offered for sale or auction at any horse sale or horse auction.

(b) *Exhibitors.* (1) Each horse owner, exhibitor, or other person having custody of or responsibility for any horse at any horse show, horse exhibition, or horse sale or auction shall, without fee, charge, assessment, or other compensation, admit any Veterinary Services representative or Designated Qualified Person appointed by management, to all areas of barns, compounds, horse vans, horse trailers, stables, stalls, paddocks, or other show, exhibition, or sale or auction grounds or related areas at any horse show, horse exhibition, or horse sale or auction, for the purpose of inspecting any such horse at any and all reasonable times.

(2) Each owner, trainer, exhibitor, or other person having custody of or responsibility for, any horse at any horse show, horse exhibition, or horse sale or auction shall promptly present his horse for inspection upon notification, orally or in writing, by any Veterinary Services representative or Designated Qualified Person appointed by management, that said horse has been selected for examination for the purpose of determining whether such horse is in compliance with the Act and regulations.

§ 11.6 Inspection space and facility requirements.

The management of every horse show, horse exhibition, or horse sale or auction, containing Tennessee Walking Horses or racking horses, shall provide, without fee, sufficient space and facilities for Veterinary Services representatives to carry out their duties under the Act and regulations at every horse show, horse exhibition, or horse sale or auction, containing Tennessee Walking Horses or racking horses, whether or not management has received prior notification or otherwise knows that such show may be inspected by Veterinary Services. The management of every horse show, horse exhibition, horse sale or auction which does not contain Tennessee Walking Horses or racking horses shall provide, without fee, such sufficient space and facilities when requested to do so by Veterinary Services representatives. With respect to such space and facilities, it shall be the responsibility of management to provide at least the following:

(a) Sufficient space in a convenient location to the horse show, horse exhibition, or horse sale or auction arena, acceptable to the Veterinary Services Show Veterinarian, in which horses may be physically, thermographically, or otherwise inspected.

(b) Protection from the elements of nature, such as rain, snow, sleet, hail, windstorm, etc., if required by the Veterinary Services Show Veterinarian.

(c) A means to control crowds or onlookers in order that Veterinary Services personnel may carry out their duties without interference and with a reasonable measure of safety, if requested by the Veterinary Services Show Veterinarian.

(d) An accessible, reliable, and convenient 110-volt electrical power source, if electrical service is available at the show, exhibition, or sale or auction site and is requested by the Veterinary Services Show Veterinarian.

(e) An appropriate area adjacent to the inspection area for designated horses to wait for inspection, and an area to be used for detention of horses.

§ 11.7 Certification and licensing of designated qualified persons (DQP's).

(a) *Basic qualifications of DQP applicants.* DQP's holding a valid, current DQP license issued in accordance with this Part may be appointed by the management of any horse show, horse exhibition, horse sale, or horse auction, as qualified persons in accordance with section 4(c) of the Act, to inspect horses to detect or diagnose soring and to otherwise inspect horses, or any records pertaining to any horse for the purpose of enforcing the Act. Individuals who may be licensed as DQP's under this part shall be:

(1) Doctors of Veterinary Medicine who are accredited in any State by the United States Department of Agriculture under Part 161 of Chapter I, Title 9 of the Code of Federal Regulations, and who are:

(i) Members of the American Association of Equine Practitioners, or

(ii) Large animal practitioners with substantial equine experience, or

(iii) Knowledgeable in the area of equine lameness as related to soring and soring practices (such as Doctors of Veterinary Medicine with a small animal practice who own, train, judge, or show horses, or Doctors of Veterinary Medicine who teach equine related subjects in an accredited college or school of veterinary medicine). Accredited Doctors of Veterinary Medicine who meet these criteria may be licensed as DQP's by a horse industry organization or association whose DQP program has been certified by the Department under this part without undergoing the formal training requirements set forth in this section.

(2) Farriers, horse trainers, and other knowledgeable horsemen whose past experience and training would qualify them for positions as horse industry organization or association stewards or judges (or their equivalent) and who have been formally trained and licensed as DQP's by a horse industry organization or association whose DQP program has been certified by the Department in accordance with this section.

(b) *Certification requirements for DQP programs.* The Department will not license DQP's on an individual basis. Licensing of DQP's will be accomplished only through DQP programs certified by the Department and initiated and maintained by horse industry organizations or associations. Any horse industry organization or association desiring Department certification to train and license DQP's under the Act shall submit to the Deputy Administrator [6] a formal request in writing for certification of its DQP program and a detailed outline of such program for Department approval. Such outline shall include the organizational structure of such organization or association and the names of the officers or persons charged with the management of the organization or association. The outline shall also contain at least the following:

(1) The criteria to be used in selecting DQP candidates and the minimum qualifications and knowledge regarding horses each candidate must have in order to be admitted to the program.

(2) A copy of the formal training program, classroom and practical, required to be completed by each DQP candidate before being licensed by such horse industry organization or association, including the minimum number of hours, classroom and practical, and the subject matter of the training program. Such training program must meet the following minimum standards in order to be certified by the Department under the Act.

(i) Two hours of classroom instruction on the anatomy and physiology of the limbs of a horse. The instructor teaching the course must be specified, and a resume of said instructor's background, experience, and qualifications to teach such course shall be provided to the Deputy Administrator.[6]

(ii) Two hours of classroom instruction on the Horse Protection Act and regulations and their interpretation. Instructors for this course must be furnished or recommended by the Department. Requests for instructors to be furnished or recommended must be made to the Deputy Administrator [6] in writing at least 30 days prior to such course.

(iii) Four hours of classroom instruction on the history of soring, the physical examination procedures necessary to detect soring, the detection and diagnosis of soring, and related subjects. The instructor teaching the course must be specified and a summary of said instructor's background, experience, and qualifications to teach such course must be provided to the Deputy Administrator.[6]

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[6] Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, 6505 Belcrest Road, Room 703, Hyattsville, MD 20782.

(iv) Four hours of practical instruction in clinics and seminars utilizing live horses with actual application of the knowledge gained in the classroom subjects covered in paragraphs (b)(2)(i), (ii), and (iii) of this section. Methods and procedures required to perform a thorough and uniform examination of a horse shall be included. The names of the instructors and a resume of their background, academic and practical experience, and qualifications to present such instruction shall be provided to the Deputy Administrator.[6] Notification of the actual date, time, duration, subject matter, and geographic location of such clinics or seminars must be sent to the Deputy Administrator[6] at least 10 days prior to each such clinic or seminar.

(v) One hour of classroom instruction regarding the DQP standards of conduct promulgated by the licensing organization or association pursuant to paragraph (d)(7) of this section.

(vi) One hour of classroom instruction on recordkeeping and reporting requirements and procedures.

(3) A sample of a written examination which must be passed by DQP candidates for successful completion of the program along with sample answers and the scoring thereof, and proposed passing and failing standards.

(4) The criteria to be used to determine the qualifications and performance abilities of DQP candidates selected for the training program and the criteria used to indicate successful completion of the training program, in addition to the written examination required in paragraph (b)(3) of this section.

(5) The criteria and schedule for a continuing education program and the criteria and methods of monitoring and appraising performance for continued licensing of DQP's by such organization or association. A continuing education program for DQP's shall consist of not less than 4 hours of instruction per year.

(6) The methods to be used to insure uniform interpretation and enforcement of the Horse Protection Act and regulations by DQP's and uniform procedures for inspecting horses for compliance with the Act and regulations; and,

(7) Standards of conduct for DQP's promulgated by the organization or association in accordance with paragraph (d)(7) of this section.

(8) A formal request for Department certification of the DQP program.

The horse industry organizations or associations that have formally requested Department certification of their DQP training, enforcement, and maintenance program will receive a formal notice of certification from the Department, or the reasons, in writing, why certification of such program cannot be approved. A current list of certified DQP programs and licensed DQP's will be published in the FEDERAL REGISTER at least once each year, and as may be further required for the purpose of deleting programs and names of DQP's that are no longer certified or licensed, and of adding the names of programs and DQP's that have been certified or licensed subsequent to the publication of the previous list.

(c) *Licensing of DQP's.* Each horse industry organization or association receiving Department certification for the training and licensing of DQP's under the Act shall:

(1) Issue each DQP licensed by such horse industry organization or association a numbered identification card bearing the name and personal signature of the DQP, a picture of the DQP, and the name and address, including the street address or post office box and zip code, of the licensing organization or association;

(2) Submit a list to the Deputy Administrator[6] of names and addresses including street address or post office box and zip code, of all DQP's that have successfully completed the certified DQP program and have been licensed under the Act and regulations by such horse industry organization or association;

(3) Notify the Department of any additions or deletions of names of li-

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[6] See footnote 6 to this section.

censed DQP's from the licensed DQP list submitted to the Department or of any change in the address of any licensed DQP or any warnings and license revocations issued to any DQP licensed by such horse industry organization or association within 10 days of such change;

(4) Not license any person as a DQP if such person has been convicted of any violation of the Act or regulations occurring after July 13, 1976, or paid any fine or civil penalty in settlement of any proceeding regarding a violation of the Act or regulations occurring after July 13, 1976, for a period of at least 2 years following the first such violation, and for a period of at least 5 years following the second such violation and any subsequent violation;

(5) Not license any person as a DQP until such person has attended and worked two recognized or affiliated horse shows, horse exhibitions, horse sales, or horse auctions as an apprentice DQP and has demonstrated the ability, qualifications, knowledge and integrity required to satisfactorily execute the duties and responsibilities of a DQP;

(6) Not license any person as a DQP if such person has been disqualified by the Secretary from making detection, diagnosis, or inspection for the purpose of enforcing the Act, or if such person's DQP license is canceled by another horse industry organization or association.

(d) *Requirements to be met by DQP's and Licensing Organizations or Associations.* (1) Any licensed DQP appointed by the management of any horse show, horse exhibition, horse sale or auction to inspect horses for the purpose of detecting and determining or diagnosing horses which are sore and to otherwise inspect horses for the purpose of enforcing the Act and regulations, shall keep and maintain the following information and records concerning any horse which said DQP recommends be disqualified or excused for any reason at such horse show, horse exhibition, horse sale or auction, from being shown, exhibited, sold or auctioned, in a uniform format required by the horse industry organization or association that has licensed said DQP:

(i) The name and address, including street address or post office box and zip code, of the show and the show manager.

(ii) The name and address, including street address or post office box and zip code, of the horse owner.

(iii) The name and address, including street address or post office box and zip code, of the horse trainer.

(iv) The name and address, including street address or post office box and zip code, of the horse exhibitor.

(v) The exhibitors number and class number, or the sale or auction tag number of said horse.

(vi) The date and time of the inspection.

(vii) A detailed description of all of the DQP's findings and the nature of the alleged violation, or other reason for disqualifying or excusing the horse, including said DQP's statement regarding the evidence or facts upon which the decision to disqualify or excuse said horse was based.

(viii) The name, age, sex, color, and markings of the horse; and

(ix) The name or names of the show manager or other management representative notified by the DQP that such horse should be excused or disqualified and whether or not such manager or management representative excused or disqualified such horse.

Copies of the above records shall be submitted by the involved DQP to the horse industry organization or association that has licensed said DQP within 72 hours after the horse show, horse exhibition, horse sale, or horse auction is over.

(2) The DQP shall inform the custodian of each horse allegedly found in violation of the Act or its regulations, or disqualified or excused for any other reason, of such action and the specific reasons for such action.

(3) Each horse industry organization or association having a Department certified DQP program shall submit a report to the Department containing the following information, from records required in paragraph (d)(1) of this section and other available sources, to the Department on a monthly basis:

(i) The identity of all horse shows, horse exhibitions, horse sales, or horse auctions that have retained the services of DQP's licensed by said organization or association during the month covered by the report. Information concerning the identity of such horse shows, horse exhibitions, horse sales, or horse auctions shall include:

(A) The name and location of the show, exhibition, sale, or auction.

(B) The name and address of the manager.

(C) The date or dates of the show, exhibition, sale, or auction.

(ii) The identity of all horses at each horse show, horse exhibition, horse sale, or horse auction that the licensed DQP recommended be disqualified or excused for any reason. The information concerning the identity of such horses shall include:

(A) The registered name of each horse.

(B) The name and address of the owner, trainer, exhibitor, or other person having custody of or responsibility for the care of each such horse disqualified or excused.

(4) Each horse industry organization or association having a Department certified DQP program shall provide, by certified mail if personal service is not possible, to the trainer and owner of each horse allegedly found in violation of the Act or its regulations or otherwise disqualified or excused for any reason, the following information:

(i) The name and date of the show, exhibition, sale, or auction.

(ii) The name of the horse and the reason why said horse was excused, disqualified, or alleged to be in violation of the Act or its regulations.

(5) Each horse industry organization or association having a Department certified DQP program shall provide each of its licensed DQP's with a current list of all persons that have been disqualified by order of the Secretary from showing or exhibiting any horse, or judging or managing any horse show, horse exhibition, horse sale, or horse auction. The Department will make such list available, on a current basis, to organizations and associations maintaining a certified DQP program.

(6) Each horse industry organization or association having a Department certified DQP program shall develop and provide a continuing education program for licensed DQP's which provides not less than 4 hours of instruction per year to each licensed DQP.

(7) Each horse industry organization or association having a Department certified DQP program shall promulgate standards of conduct for its DQP's, and shall provide administrative procedures within the organization or association for initiating, maintaining, and enforcing such standards. The procedures shall include the causes for and methods to be utilized for canceling the license of any DQP who fails to properly and adequately carry out his duties. Minimum standards of conduct for DQP's shall include the following:

(i) A DQP shall not exhibit any horse at any horse show or horse exhibition, or sell, auction, or pruchase any horse sold at a horse sale or horse auction at which he or she has been appointed to inspect horses;

(ii) A DQP shall not inspect horses at any horse show, horse exhibition, horse sale or horse auction in which a horse or horses owned by a member of the DQP's immediate family or the DQP's employer are competing or are being offered for sale;

(iii) A DQP shall follow the uniform inspection procedures of his certified organization or association when inspecting horses; and

(iv) The DQP shall immediately inform management of each case regarding any horse which, in his opinion, is in violation of the Act or regulations.

(e) *Prohibition of appointment of certain persons to perform duties under the Act.* The management of any horse show, horse exhibition, horse sale, or horse auction shall not appoint any person to detect and diagnose horses which are sore or to otherwise inspect horses for the purpose of enforcing the Act, if that person:

(1) Does not hold a valid, current DQP license issued by a horse industry organization or association having a DQP program certified by the Department.

(2) Has had his DQP license canceled by the licensing organization or association.

(3) Is disqualified by the Secretary from performing diagnosis, detection, and inspection under the Act, after notice and opportunity for a hearing,[7] when the Secretary finds that such person is unfit to perform such diagnosis, detection, or inspection because he has failed to perform his duties in accordance with the Act or regulations, or because he has been convicted of a violation of any provision of the Act or regulations occurring after July 13, 1976, or has paid any fine or civil penalty in settlement of any proceeding regarding a violation of the Act or regulations occurring after July 13, 1976.

(f) *Cancellation of DQP license.* (1) Each horse industry organization or association having a DQP program certified by the Department shall issue a written warning to any DQP whom it has licensed who violates the rules, regulations, by-laws, or standards of conduct promulgated by such horse industry organization or association pursuant to this section, or who carries out his duties and responsibilities in a less than satisfactory manner, and shall cancel the license of any DQP after a second violation. Upon cancellation of his DQP license, the DQP may, within 30 days thereafter, request a hearing before a review committee of not less than three persons appointed by the licensing horse industry organization or association. If the review committee sustains the cancellation of the license, the DQP may appeal the decision of such committee to the Deputy Administrator within 30 days from the date of such decision, and the Deputy Administrator shall make a final determination in the matter. If the Deputy Administrator finds, after providing the DQP whose license has been canceled with a notice and an opportunity for a hearing,[7] that there is sufficient cause for the committee's determination regarding license cancellation, he shall issue a decision sustaining such determination. If he does not find that there was sufficient cause to cancel the license, the licensing organization or association shall reinstate the license.

(2) Each horse industry organization or association having a Department certified DQP program shall cancel the license of any DQP licensed under its program who has been convicted of any violation of the Act or regulations or of any DQP who has paid a fine or civil penalty in settlement of any alleged violation of the Act or regulations if such alleged violation occurred after July 13, 1976.

(g) *Revocation of DQP program certification of horse industry organizations or associations.* Any horse industry organization or association having a Department certified DQP program which fails to comply with the requirements contained in this section may have such certification of its DQP program revoked unless, upon written notification from the Department of such failure to comply with the requirements in this section, such organization or association takes immediate action to rectify such failure and takes appropriate steps to prevent a recurrence of such non-compliance within the time period specified in the Department notification, or otherwise adequately explains such failure to comply. Any horse industry organization or association whose DQP program certification has been revoked may appeal such revocation to the Deputy Administrator[6] in writing within 30 days after the date of such revocation and, if requested, shall be afforded an opportunity for a hearing.[7] All DQP licenses issued by a horse industry organization or association whose DQP program certification has been revoked shall expire 30 days after the date of such revocation, or 15 days after the date the revocation becomes final after appeal, unless they are transferred to a horse industry organization or association having a program currently certified by the Department.

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[7] Hearing would be in accordance with the Uniform Rules of Practice for the Department of Agriculture in Subpart H of Part 1, Subtitle A, Title 7, Code of Federal Regulations (7 CFR 1.130 *et seq.*)

[6, 7] See previous footnotes 6 and 7.

(Approved by the Office of Management and Budget under control number 0579-0056)

[44 FR 1563, Jan. 5, 1979, as amended at 44 FR 25182, Apr. 27, 1979; 48 FR 57471, Dec. 30, 1983]

§ 11.20 Responsibilities and liabilities of management.

(a) The management of any horse show, horse exhibition, or horse sale or auction which does not appoint and retain a DQP shall be responsible for identifying all horses that are sore or otherwise in violation of the Act or regulations, and shall disqualify or disallow any horses which are sore or otherwise in violation of the Act or regulations from participating or competing in any horse show, horse exhibition, horse sale, or horse auction. Horses entered for sale or auction at a horse sale or horse auction must be identified as sore or otherwise in violation of the Act or regulations prior to the sale or auction and prohibited from entering the sale or auction ring. Sore horses or horses otherwise in violation of the Act or regulations that have been entered in a horse show or horse exhibition for the purpose of show or exhibition must be identified and excused prior to the show or exhibition. Any horses found to be sore or otherwise in violation of the Act or regulations during actual participation in the show or exhibition, must be removed from further participation prior to the tyeing of the class or the completion of the exhibition. All horses tyed first in each Tennessee Walking Horse or racking horse class or event at any horse show or horse exhibition shall be inspected after being shown or exhibited to determine if such horses are sore or otherwise in violation of the Act or regulations.

(b)(1) The management of any horse show, horse exhibition, horse sale or auction which designates and appoints a Designated Qualified Person (or persons) to inspect horses shall accord said DQP access to all records and areas of the grounds of such show, exhibition, sale, or auction and the same right to inspect horses and records as is accorded to any Veterinary Services representative. Further, management shall not take any action which would interfere with or influence said DQP in carrying out his duties or making decisions concerning whether or not any horse is sore or otherwise in violation of the Act or regulations. In the event management is dissatisfied with the performance of a particular DQP, including disagreement with decisions concerning violations, management shall not dismiss or otherwise interfere with said DQP during the DQP's appointed tour of duty.[8] However, management should immediately notify, in writing, the Department[6] and the organization or association that licensed the DQP, as to why the performance of said DQP was inadequate or otherwise unsatisfactory. Management which designates and appoints a DQP shall immediately disqualify or disallow from being shown, exhibited, sold, or auctioned any horse identified by the DQP to be sore or otherwise in violation of the Act or regulations or any horse otherwise known by management to be sore or in violation of the Act or regulations. Should management fail to disqualify or disallow from being shown, exhibited, sold or auctioned any such horse, said management shall assume full responsibility for and liabilities arising from the showing, exhibition, sale, or auction of said horses.

(2) The DQP shall physically inspect: (i) All Tennessee Walking Horses and racking horses entered for sale or auction, (ii) all Tennessee Walking Horses and racking horses entered in any animated gait class (whether under saddle, horse to cart, or otherwise), (iii) all Tennessee Walking Horses and racking horses entered for exhibition before they are admitted to be shown, exhibited, sold, or auctioned, and (iv) all Tennessee Walking Horses and racking horses tyed first in their class or event at any horse show, horse exhibition, horse sale, or horse auction. Such inspection shall be for the purpose of determining whether any such horses are in violation of the Act or regulations. Such physical examination may be conducted in any manner deemed nec-

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[6] See footnote 6 to § 11.7.

[8] The duration of the show, exhibition, or sale or auction.

essary by the DQP in order to determine whether any such horses are sore. The DQP shall observe horses in the warmup ring and during actual performances whenever possible, and shall inspect any Tennessee Walking Horse or racking horse at any time he deems necessary to determine whether any such horse shown, exhibited, sold, or auctioned is in violation of the Act or regulations. If present at other shows, he shall examine any horse which he determines should be examined for compliance with the Act and regulations.

(3) The DQP shall immediately report, to the management of any horse show, horse exhibition, or horse sale or auction, any horse which, in his opinion, is sore or otherwise in violation of the Act or regulations. Such report shall be made, whenever possible, before the show class or exhibitioin involving said horse has begun or before said horse is offered for sale or auction.

(Approved by the Office of Management and Budget under control number 0579-0056)

[44 FR 25182, Apr. 27, 1979, as amended at 48 FR 57471, Dec. 30, 1983]

§ 11.21 Records required and disposition thereof.

(a) The management of any horse show, horse exhibition, or horse sale or auction, that contains Tennessee Walking Horses or racking horses, shall maintain for a period of at least 90 days following the closing date of said show, exhibition, or sale or auction, all pertinent records containing:

(1) The dates and place of the horse show, horse exhibition, horse sale, or horse auction.

(2) The name and address (including street address or post office box number and ZIP code) of the sponsoring organization.

(3) The name and address of the horse show, exhibition, horse sale or horse auction management.

(4) The name and address (including street address or post office box number and ZIP code) of the DQP, if any, employed to conduct inspections under § 11.20; and, the name of the horse industry organization or association certifying the DQP.

(5) The name and address (including street address or post office box number, and ZIP code) of each show judge.

(6) A copy of each class or sale sheet containing the names of horses, the names and addresses (including street address, post office box and ZIP code) of horse owners, the exhibitor number and class number, or sale number assigned to each horse, the show class or sale lot number, and the name and address (including street address, post office box, and ZIP code) of the person paying the entry fee and entering the horse in a horse show, horse exhibition, or horse sale or auction.

(7) A copy of the official horse show, horse exhibition, horse sale, or horse auction program, if any such program has been prepared.

(8) The identification of each horse, including the name of the horse, the name and address (including street address, post office box, and ZIP code) of the owner, the trainer, the rider or other exhibitor, and the location (including street address, post office box, and ZIP code) of the home barn or other facility where the horse is stabled.

(b) The management of any horse show, horse exhibition, or horse sale or auction containing Tennessee Walking Horses or racking horses shall designate a person to maintain the records required in this section.

(c) The management of any horse show, horse exhibition, or horse sale or auction containing Tennessee Walking Horses or racking horses shall furnish to any Veterinary Services representative, upon request, the name and address (including street address, or post office box, and ZIP code) of the person designated by the sponsoring organization or manager to maintain the records required by this section.

(d) The Deputy Administrator may, in specific cases, require that a horse show, horse exhibition, or horse sale or auction records be maintained by management for a period in excess of 90 days.

(Approved by the Office of Management and Budget under control numbers 0579-0056, and 0579-0058)

(44 U.S.C. 3506)

[44 FR 25179, Apr. 27, 1979, as amended at 48 FR 57471, Dec. 30, 1983]

§ 11.22 Inspection of records.

(a) The management of any horse show, horse exhibition, or horse sale or auction shall permit any Veterinary Services representative, upon request, to examine and make copies of any and all records pertaining to any horse, either required in any part of the regulations, or otherwise maintained, during ordinary business hours or such other times as may be mutually agreed upon. A room, table, or other facilities necessary for proper examination of such records shall be made available to the Veterinary Services representative.

(b) Horse industry organizations or associations who train, maintain, and license DQP's under a certified DQP program shall permit any Veterinary Services representative, upon request, to examine and copy any and all records relating to the DQP program which are required by any part of the regulations. Such requests shall be made during ordinary business hours or such other times as mutually agreed upon. A room, table or other facilities necessary for proper examination shall be made available upon the request of the Veterinary Services representative.

§ 11.24 Reporting by management.

(a) Within 5 days following the conclusion of any horse show, horse exhibition, or horse sale or auction, containing Tennessee Walking Horses or racking horses, the managements of such show, exhibition, sale or auction shall submit to the Area Veterinarian in Charge[1] for the State in which the show, exhibition, sale or auction was held, the information required by § 11.21(a)(1) through § 11.21(a)(6) for each horse excused or disqualified by management or its representatives from being shown, exhibited, sold or auctioned, and the reasons for such action. If no horses are excused or disqualified, the management shall submit a report so stating.

(b) Within 5 days following the conclusion of any horse show, horse exhibition, or horse sale or auction which does not contain Tennessee Walking Horses or racking horses, the management of such show, exhibition, sale or auction shall inform the Area Veterinarian in Charge for the State in which the show, exhibition, sale or auction was held, of any case where a horse was excused or disqualified by management or its representatives from being shown, exhibited, sold or auctioned because it was found to be sore.

(Approved by the Office of Management and Budget under control number 0579-0056)

[44 FR 25179, Apr. 27, 1979, as amended at 48 FR 57471, Dec. 30, 1983]

§ 11.40 Prohibitions and requirements concerning persons involved in transportation of certain horses.

(a) Each person who ships, transports, or otherwise moves, or delivers or receives for movement, any horse with reason to believe such horse may be shown, exhibited, sold or auctioned at any horse show, horse exhibition, or horse sale or auction, shall allow and assist in the inspection of such horse at any such show, exhibition, sale, or auction to determine compliance with the Act as provided in § 11.4 of the regulations and shall furnish to any Veterinary Services representatives upon his request the following information:

(1) Name and address (including street address, post office box, and ZIP code) of the horse owner and of the shipper, if different from the owner or trainer.

(2) Name and address (including street address, post office box, and ZIP code) of the horse trainer.

(3) Name and address (including street address, post office box, and ZIP code) of the carrier transporting the horse, and of the driver of the means of conveyance used.

(4) Origin of the shipment and date thereof, and,

(5) Destination of shipment.

(Approved by the Office of Management and Budget under control number 0579-0056)

[44 FR 25179, Apr. 27, 1979, as amended at 48 FR 57471, Dec. 30, 1983]

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[1] See footnote 1 to § 11.1.

§ 11.41 Reporting required of horse industry organizations or associations.

Each horse industry organization or association which sponsors, or which sanctions any horse show, horse exhibition, or horse sale or auction, shall furnish the Department[6] by March 1 of each year with all such organization or association rulebooks, and disciplinary procedures for the previous year pertaining to violations of the Horse Protection Act or regulations, applicable to such horse show, horse exhibition, or horse sale or auction. Rulebooks and information relating to disciplinary procedures for violations of the Horse Protection Act or regulations should be readily available to all exhibitors, trainers, and owners of horses at such show, exhibition, sale, or auction. Each horse industry organization or association shall furnish the Department[6] with a quarterly report of all disciplinary actions taken against the management or any horse show, horse exhibition, horse sale, or horse auction, any exhibitor, or any licensed DQP, for violation of the Horse Protection Act or regulations, and the results thereof.

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[44 FR 25179, Apr. 27, 1979, as amended at 48 FR 57471, Dec. 30, 1983]

PART 12—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE HORSE PROTECTION ACT

Subpart A—General

Sec.
12.1 Scope and applicability of rules of practice.

Subpart B—Supplemental Rules of Practice

12.10 Stipulations.

Subpart A—General

§ 12.1 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the Department of Agriculture promulgated in Subpart H of Part 1, Subtitle A, Title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings under section 6(a) of the Horse Protection Act of 1970 (15 U.S.C. 1825(a)) and sections 6 (b) and (c) of the Horse Protection Act (15 U.S.C. 1825 (b) and (c)). In addition, the Supplemental Rules of Practice set forth in Subpart B of this part shall be applicable to such proceedings.

(84 Stat. 1406; 15 U.S.C. 1828)

[42 FR 10959, Feb. 25, 1977]

Subpart B—Supplemental Rules of Practice

§ 12.10 Stipulations.

(a) At any time prior to the issuance of a complaint seeking a civil penalty under the Act, the Administrator, in his discretion, may enter into a stipulation with any person in which:

(1) The Administration gives notice of an apparent violation of the Act or the regulations issued thereunder by such person and affords such person an opportunity for a hearing regarding the matter as provided by the Act;

(2) Such person expressly waives hearing and agrees to a specified order including an agreement to pay a specified civil penalty within a designated time; and

(3) The Administrator agrees to accept the specified order including a civil penalty in settlement of the particular matter involved if it is paid within the designated time.

(b) If the specified penalty is not paid within the time designated in such a stipulation, the amount of the stipulated penalty shall not be relevant in any respect to the penalty which may be assessed after issuance of a complaint.

(84 Stat. 1406; 15 U.S.C. 1828)

[42 FR 10960, Feb. 25, 1977]

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[6] See footnote 6 to § 11.7.

SUBCHAPTER B—COOPERATIVE CONTROL AND ERADICATION OF LIVESTOCK OR POULTRY DISEASES

PART 49—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER CERTAIN ACTS

Subpart A—General

Sec.
49.1 Scope and applicability of rules of practice.

Subpart B—Supplemental Rules of Practice

49.10 Stipulations.

AUTHORITY: Secs. 3-7, 23 Stat. 32, as amended; secs. 2 and 3, 32 Stat. 792, as amended; secs. 1, 3, 4, and 6, 33 Stat. 1264, 1265, as amended; sec. 11, 58 Stat. 734, as amended; sec. 2, 65 Stat. 693, as amended; secs. 3 and 4, 76 Stat. 130; sec. 6, 76 Stat. 131, as amended; sec. 11, 76 Stat. 132; 21 U.S.C. 111, 112, 114, 114a, 114a-1, 115, 117, 120, 122, 123, 125-127, 134b, 134c, 134e, 134f; 7 CFR 2.17, 2.51, 371.2(d).

SOURCE: 48 FR 30094, June 30, 1983, unless otherwise noted.

Subpart A—General

§ 49.1 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the Department of Agriculture promulgated in Subpart H of Part 1, Subtitle A, Title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings under the following statutory provisions:

Act of May 29, 1884, commonly known as the Animal Industry Act, Section 7, as amended (21 U.S.C. 117),

Act of February 2, 1903, commonly known as the Cattle Contagious Diseases Act of 1903, Section 3, as amended (21 U.S.C. 122),

Act of March 3, 1905, Section 6, as amended (21 U.S.C. 127),

Act of July 2, 1962, Section 6(a), as amended (21 U.S.C. 134e).

In addition, the Supplemental Rules of Practice set forth in Subpart B of this part shall be applicable to such proceedings.

Subpart B—Supplemental Rules of Practice

§ 49.10 Stipulations.

(a) At any time prior to the issuance of a complaint seeking a civil penalty under any of the Acts listed in § 49.1, the Administrator, in his discretion, may enter into a stipulation with any person in which:

(1) The Administrator or the Administrator's delegate gives notice of an apparent violation of the applicable Act, or the regulations issued thereunder, by such person and affords such person an opportunity for a hearing regarding the matter as provided by such Act;

(2) Such person expressly waives hearing and agrees to pay a specified penalty within a designated time; and

(3) The Administrator agrees to accept the penalty in settlement of the particular matter involved if the penalty is paid within the designated time.

(b) If the penalty is not paid within the time designated in such a stipulation, the amount of the stipulated penalty shall not be relevant in any respect to the penalty which may be assessed after issuance of a complaint.

PART 50—BOVINE TUBERCULOSIS INDEMNITY

Sec.
50.1 Definitions.
50.2 Cooperation with States.
50.3 Payment to owners for animals destroyed.
50.4 Determination of existence of or exposure to tuberculosis.
50.5 Record of tests.
50.6 Identification of animals to be destroyed because of tuberculosis.
50.7 Destruction of animals.
50.8 Payment of expenses for transportation and disposal of carcasses of affected animals.
50.9 Appraisals.
50.10 Report of appraisals.
50.11 Report of salvage proceeds.
50.12 Claims for indemnity.
50.13 Disinfection of premises, conveyances, and materials.

Sec.
50.14 Claims not allowed.
50.15 Part 53 of this chapter not applicable.

AUTHORITY:21 U.S.C. 111-113, 114, 114a, 114a-1, 120, 121, 125, 134b; 7 CFR 2.17, 2.51, and 37.2(d).

SOURCE: 40 FR 27009, June 26, 1975, unless otherwise noted.

§ 50.1 Definitions.

For the purposes of this part, the following terms shall be construed, respectively, to mean:

(a) "Department": The United States Department of Agriculture.

(b) "Veterinary Services": Veterinary Services, Animal and Plant Health Inspection Service, USDA.

(c) "Deputy Administrator": The Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, USDA, or any other Veterinary Services official to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(d) "Veterinarian in Charge": The Veterinary official of Veterinary Services, Animal and Plant Health Inspection Service, USDA, who is assigned by the Deputy Administrator to supervise and perform official animal health work of the Animal and Plant Health Inspection Service in the State concerned.

(e) "Veterinary Services Representative": A veterinarian or other person employed by Veterinary Services, Animal and Plant Health Inspection Service, USDA, in animal health activities who is authorized to perform the function involved.

(f) "State": Any State, territory, the District of Columbia, or Puerto Rico.

(g) "Accredited Veterinarian": An accredited veterinarian as defined in Part 160 of this chapter.

(h) "Mortgage": Any mortgage, lien or other security or interest that is recorded under State law or identified in the indemnity claim form filed under § 50.12 and held by any person other than the one claiming indemnity.

(i) "Person": Any individual, corporation, company, association, firm, partnership, society, or joint stock company, or any organized group of any of the foregoing.

(j) "Owner": Any person who has a legal or rightful title to cattle whether or not they are subject to a mortgage.

(k) "Destroyed": Condemned under State authority and destroyed by slaughter or by death otherwise.

(l) "Animals": Any mammalian species which may serve as a carrier or reservoir of tuberculosis.

(m) "Herd": Any group of animals (of like kind) maintained on common ground for any purpose, or two or more groups of animals (of like kind) under common ownership or supervision, geographically separated but which have an interchange or movement of cattle without regard to health status.

(n) "Herd Depopulation": Removal by slaughter or other means of destruction of all cattle in a herd or from specific premises or under common ownership prior to restocking with new animals.

(o) "Registered Cattle": Cattle for which individual records of ancestry are recorded and maintained, and for which individual registration certificates are issued and recorded by a recognized breed association whose purpose is the improvement of the breed.

(p) "Permit": A permit for movement of cattle direct to slaughter listing the disease, status and identification of the animal, where consigned, cleaning and disinfecting requirements, and proof of slaughter certification.

(q) "Tuberculosis": The contagious, infectious, and communicable disease of cattle caused by *Mycobacterium bovis*.

[40 FR 27009, June 26, 1975, as amended at 45 FR 32287, May 16, 1980]

§ 50.2 Cooperation with States.

The Deputy Administrator has been delegated the authority to cooperate with the proper State authorities in the eradication of tuberculosis and to pay Federal indemnities for the destruction of cattle affected with or exposed to tuberculosis.

§ 50.3 Payment to owners for animals destroyed.

(a) *Affected cattle.* The Department may pay owners an indemnity for cattle affected with tuberculosis not to exceed $750 for each animal, but any joint State-Federal indemnity payments, plus salvage, must not exceed the appraised value of each animal.

(b) *Herd depopulation—cattle.* The Deputy Administrator may authorize the payment of Federal indemnity to owners of cattle destroyed because of tuberculosis, not to exceed $450 for any animal which is a part of a known affected herd, when it has been determined by the Deputy Administrator that the destruction of all the exposed cattle in the herd will contribute to the Tuberculosis Eradication Program; but, the joint State-Federal indemnity payments, plus salvage, must not exceed the appraised value of each animal.

(c) *Exposed cattle.* The Deputy Administrator may authorize the payment of Federal indemnity to owners of cattle destroyed because of tuberculosis not to exceed $450 for any animal which has been found by Veterinary Services to have been exposed by reason of association with tuberculous cattle, when it has been determined by the Deputy Administrator that the destruction of the exposed cattle will contribute to the Tuberculosis Eradication Program; but, the joint State-Federal indemnity payments, plus salvage, must not exceed the appraised value of each animal.

(d) *Exposed swine.* The Deputy Administrator may authorize the payment of Federal indemnity to owners of swine destroyed because of tuberculosis not to exceed $200 for any animal, when such animals are found by Veterinary Services to be exposed to tuberculosis by reason of association with a herd of cattle destroyed under § 50.3(b); but, the joint State-Federal indemnity payments, plus salvage, must not exceed the appraised value of each animal.

(e) *Bison.* The provisions of this part applying to cattle shall also apply to bison in herds in South Dakota found in June 1984 to be foci of tuberculosis infection and to any other bison affected with or exposed to tuberculosis because of such South Dakota foci of tuberculosis infection.

(Secs. 3, 4, 5, 11, and 13, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; sec. 3, 33 Stat. 1265, as amended; sec. 3, 76 Stat. 130; 21 U.S.C. 111-113, 114, 114a, 114a-1, 120, 121, 125, 134b; 7 CFR 2.17, 2.51, and 371.2(d))

[45 FR 32287, May 16, 1980, as amended at 49 FR 28041, July 10, 1984; 49 FR 44273, Nov. 6, 1984]

§ 50.4 Determination of existence of or exposure to tuberculosis.

(a) Cattle are classified as affected with tuberculosis on the basis of an intradermal tuberculin test applied by a Federal, State, or an accredited veterinarian or by other diagnostic procedure approved in advance by the Deputy Administrator.

(b) Cattle are classified as exposed to tuberculosis when such animals (1) are part of a known infected herd, or (2) are found to have moved from an infected herd before the time infection was disclosed in such herd and after the time such herd had apparently become infected, or (3) are found to have been exposed by virtue of nursing a reactor dam: *Provided,* That cattle classified as exposed to tuberculosis shall be removed direct to slaughter.

§ 50.5 Record of tests.

When any animal in a herd of cattle is classified by a Veterinary Services or State representative or accredited veterinarian as a reactor to a test for tuberculosis, a complete test record shall be made for such herd, including the reactor tag number of each reacting animal and the registration name and number of each reacting registered animal. A form acceptable to Veterinary Services shall be used for the record of any herd having any reactor to a tuberculin test. A copy of the applicable test record shall be given to the owner of any such herd, and one copy of each such record shall be furnished to the appropriate State veterinarian's office.

§ 50.6 Identification of animals to be destroyed because of tuberculosis.

Animals to be destroyed because of tuberculosis must be identified within 15 days after being classified as reactors or otherwise condemned because of tuberculosis, except that the appropriate Veterinarian in Charge, for reasons satisfactory to him, may extend the time limit for identification to 30 days when a request for such extension is received by him prior to the expiration date of the original 15-day period allowed, and the Deputy Administrator may extend the time limit for identification beyond 30 days, upon request in specific cases and for reasons satisfactory to him.

(a) *Reactor cattle.* Reactor cattle shall be identified by branding the letter "T" on the left jaw not less than 2 nor more than 3 inches high and by tagging with an approved metal eartag bearing a serial number and inscription "U.S. Reactor" or a similar State reactor tag suitably attached to the left ear of each animal.

(b) *Exposed cattle.* Exposed cattle shall be identified by branding the letter "S" on the left jaw not less than 2 nor more than 3 inches high and by tagging with an approved metal eartag bearing a serial number attached to either ear of each animal; *Provided, however,* That in lieu of branding they may be accompanied to slaughter by a Veterinary Services or State representative; or be shipped in vehicles closed with official seals.

(c) *Exposed swine.* Swine destroyed under the provisions of § 50.3(d) shall be identified by tagging with a serially numbered metal eartag attached to either ear. All such animals to be destroyed shall be transported to the place of destruction in vehicles closed with seals provided by Veterinary Services or shall be accompanied to the place of destruction by a Veterinary Services or State representative: *Provided, however,* That animals destroyed and disposed of under the direct supervision of a Veterinary Services or State representative on the premises where they were exposed do not require individual identification.

[40 FR 27009, June 26, 1975, as amended at 45 FR 32287, May 16, 1980; 50 FR 40963, Oct. 8, 1985]

§ 50.7 Destruction of animals.

(a) *Slaughter or disposal.* Animals to be destroyed because of tuberculosis must be shipped direct to slaughter under permit to a Federal or State inspected slaughtering establishment or be disposed of by rendering, burial, or incinerating in an approved manner under supervision of a Veterinary Services or State employee.

(b) *Time limit for destruction of animals.* Animals for which Federal indemnity may be paid because of tuberculosis must be destroyed and carcass disposal completed within 15 days after the date of appraisal, except that the appropriate Veterinarian in Charge, for reasons satisfactory to him, may extend the time limit for slaughter to 30 days when request for such extension is received by him prior to the expiration of the original 15-day period allowed, and the Deputy Administrator may extend the time limit for slaughter beyond 30 days, upon request in specific cases and for reasons satisfactory to him.

[40 FR 27009, June 26, 1975, as amended at 45 FR 32287, May 16, 1980]

§ 50.8 Payment of expenses for transportation and disposal of carcasses of affected animals.

The Department may pay, when approved in advance in writing by the Veterinarian in Charge, one-half the expenses for destruction, burial, incineration, rendering, or otherwise disposing of affected cattle and one-half the expenses of transportation of affected cattle to the point where disposal shall take place. Claims for such payment shall be made on forms furnished by Veterinary Services and shall be signed by a Veterinary Services or State representative or jointly and by the owner certifying his acceptance of the amount claimed. No portion of expenses of disposal or transportation provided by the owner of affected animals shall be paid by the Department.

[45 FR 32288, May 16, 1980]

§ 50.9 Appraisals.

Animals to be destroyed because of tuberculosis under § 50.3 shall be appraised within 15 days after being classified as affected or after otherwise being condemned because of tuberculosis, except that the Veterinarian in Charge, for reasons satisfactory to him, may extend the time limit for appraisal to 30 days when a request for such extension is received by him prior to the expiration date of the original 15-day period allowed, and the Deputy Administrator may extend the time limit for appraisal beyond 30 days, upon request in specific cases and for reasons satisfactory to him. The appraisal shall be by an independent professional appraiser for reasons satisfactory to him. When animals are thus appraised, due consideration shall be given to their breeding value as well as to their dairy or meat value. Animals presented for payment as registered shall be accompanied by their registration papers. If the registration papers are temporarily not available, or if the cattle are less than 3 years old and unregistered, the appropriate Veterinarian in Charge may grant a reasonable time for the presentation of their registration papers. Veterinary Services may decline to accept any appraisal that appears to be unreasonable or out of proportion to the value of animals of like quality.

[45 FR 32288, May 16, 1980, as amended at 50 FR 40963, Oct. 8, 1985]

§ 50.10 Report of appraisals.

Appraisals of cattle made in accordance with § 50.9 shall be recorded on forms furnished by Veterinary Services. The appraisal form shall be signed by the appraiser and by the owner certifying his acceptance of the appraisal. The "date of appraisal" shall be the date that the owner signs the appraisal form. The original of the appraisal form and as many copies thereof as may be required for Veterinary Services, the State, and the owner of the animals shall be sent to the appropriate Veterinarian in Charge.

§ 50.11 Report of salvage proceeds.

A report of the salvage derived from the sale of each animal on which a claim for indemnity may be made under the provisions of § 50.3 shall be made on a salvage form acceptable to Veterinary Services which shall be signed by the purchaser or his agent or by the selling agent handling the animals. If the cattle are sold by the pound, the salvage form shall show the weight, price per pound, gross receipts, expenses if any, and net proceeds. If the cattle are not sold on a per pound basis, the net purchase price of each animal must be stated on the salvage form and an explanation showing how the amount was arrived at must be submitted. In the event the animals are not disposed of through regular slaughterers or through selling agents, the owner shall furnish, in lieu of the salvage form, an affidavit showing the amount of salvage obtained by him and shall certify that such amount is all that he has received or will receive as salvage for said animals. In an emergency, a certificate executed by the appropriate Veterinarian in Charge will be acceptable in lieu of the owner's affidavit. The salvage shall be considered to be the net amount received for an animal after deducting freight, truckage, yardage, commission, slaughtering charges, and similar costs. The original of the salvage form or the affidavit of the owner or certificate of the appropriate Veterinarian in Charge, furnished in lieu thereof, shall be furnished to the Veterinarian in charge if it is not already in his possession. Additional copies may be furnished to the State officials, if required. Destruction of animals by burial, incineration or other disposal of carcasses shall be supervised by a Veterinary Services or State representative who shall prepare and transmit to the Veterinarian in Charge a report identifying the animals and showing the disposition thereof.

(Approved by the Office of Management and Budget under control number 0579-0001)

[40 FR 27009, June 26, 1975, as amended at 48 FR FR 57471, Dec. 30, 1983]

§ 50.12 Claims for indemnity.

Claims for Federal indemnity for cattle destroyed because of tuberculosis shall be presented on indemnity claim forms furnished by Veterinary Services, on which the owner of the animals covered thereby shall certify that the animals are or are not, subject to any mortgage as defined in this Part. If the owner states there is a mortgage, the Veterinary Services indemnity claim form shall be signed by the owner and by each person holding a mortgage on the animals consenting to the payment of any indemnity allowed to the person specified thereon. Payment will be made only if the Veterinary Services indemnity claim form has been approved by a proper State official and if payment of the claim has been recommended by the appropriate Veterinarian in Charge or an official designated by him. On claims for indemnity made under the provisions of § 50.3, the Veterinarian in Charge or official designated by him shall record on the Veterinary Services indemnity claim form the amount of Federal and State indemnity payments that appear to be due to the owner of the animals. The owner of the animals shall be furnished a copy of the Veterinary Services indemnity claim form. The Veterinarian in Charge or official designated by him shall then forward the Veterinary Services indemnity claim form to the appropriate official for further action on the claim. No charges for holding the cattle on the farm pending slaughter or for trucking by the owner shall be so deducted or otherwise paid by the Department.

§ 50.13 Disinfection of premises, conveyances, and materials.

All premises, including all structures, holding facilities, conveyances, or materials which are determined by the appropriate Veterinarian in Charge to constitute a health hazard to humans or animals because of tuberculosis shall be properly cleaned and disinfected, in accordance with procedures approved by the Department, within 15 days after the removal of tuberculosis affected or exposed cattle except that the Veterinarian in Charge, for reasons satisfactory to him, may extend the time limit for disinfection to 30 days when request for such extension is received by him prior to the expiration date of the original 15-day period allowed.

§ 50.14 Claims not allowed.

Claims for compensation for cattle destroyed because of tuberculosis shall not be allowed if any of the following circumstances exist:

(a) If the claimant has failed to comply with any of the requirements of this part.

(b) If all cattle 2 years of age or over in the claimants herd have not been tested for tuberculosis under Veterinary Services or State supervision: *Provided, however,* That cattle destroyed because of tuberculosis under § 50.3(b) and § 50.3(c) are exempt from this requirement, if the cattle are subjected to a post-mortem examination for tuberculosis by a Federal or State veterinarian.

(c) If there is substantial evidence that the owner or his agent has in any way been responsible for any attempt unlawfully or improperly to obtain indemnity funds for such animals.

(d) If at the time of test or condemnation, the cattle belonged to or were upon the premises of any person to whom they had been sold, shipped, or delivered for slaughter unless or until all of the cattle remaining on the premises or in the herd from which the tested or condemned cattle originated are tested or otherwise examined for tuberculosis in a manner satisfactory to the Deputy Administrator or his designated representative.

(e) If the cattle affected with tuberculosis have been added to the herd while the herd was under quarantine for tuberculosis.

[40 FR 27009, June 26, 1975, as amended at 45 FR 32288, May 16, 1980]

§ 50.15 Part 53 of this chapter not applicable.

No claim for Federal indemnity for cattle destroyed because of tuberculosis shall hereafter be paid under the regulations contained in Part 53 of this chapter, but all such claims shall be presented and paid pursuant to and in compliance with the regulations contained in this part.

PART 51—ANIMALS DESTROYED BECAUSE OF BRUCELLOSIS

Sec.
51.1 Definitions.
51.2 Cooperation with States.
51.3 Payment to owners for animals destroyed.
51.4 Record of tests.
51.5 Identification of animals to be destroyed because of brucellosis.
51.6 Destruction of animals; time limit for destruction of animals.

Sec.
51.7 Claims for indemnity.
51.8 Disinfection of premises, conveyances, and materials.
51.9 Claims not allowed.
51.10 Part 53 of this chapter not applicable.

AUTHORITY: 21 U.S.C. 111-113, 114, 114a, 114a-1, 120, 121, 125, 134b; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 42 FR 64336, Dec. 23, 1977, unless otherwise noted.

§ 51.1 Definitions.

For the purposes of this part, the following terms shall be construed, respectively, to mean:

(a) *Department.* The United States Department of Agriculture.

(b) *Veterinary Services.* Veterinary Services, Animal and Plant Health Inspection Service, USDA.

(c) *Deputy Administrator.* The Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, USDA, or any other Veterinary Services official to whom authority has heretofore lawfully been delegated or may hereafter be delegated to act in his stead.

(d) *Veterinarian in Charge.* The Veterinary official of Veterinary Services, Animal and Plant Health Inspection Service, USDA, who is assigned by the Deputy Administrator to supervise and perform official animal health work of the Animal and Plant Health Inspection Service, in the State concerned.

(e) *Veterinary Services Representative.* A veterinarian or other person employed by Veterinary Service, Animal and Plant Health Inspection Service, USDA, in animal health activities who is authorized to perform the function involved.

(f) *State.* Any State, Territory, Possession, the District of Columbia, or Puerto Rico.

(g) *Accredited Veterinarian.* An accredited veterinarian as defined in Part 160 of this chapter.

(h) *Mortgage.* Any mortgage, lien, or other security or interest that is recorded under State law or identified in the indemnity claim form filed under § 51.7 and held by any person other than the one claiming indemnity.

(i) *Person.* Any individual, corporation, company, association, firm, partnership, society, or joint stock company, or other legal entity.

(j) *Owner.* Any person who has a legal or rightful title to animals whether or not they are subject to a mortgage.

(k) *Destroyed.* Condemned under State authority and slaughter or otherwise dies.

(l) *Official vaccinate.* A female bovine animal of a dairy breed vaccinated subcutaneously against brucellosis while from 2 to 6 months (60 to 179 days) of age or a female bovine animal of a beef breed vaccinated subcutaneously against brucellosis while from 2 to 10 months (60 to 299 days) of age, under the supervision of a Federal or State Veterinary official, with a vaccine approved by Veterinary Services, permanently identified as an official vaccinate; and reported at the time of vaccination to the appropriate State or Federal agency cooperating in the eradication of brucellosis: *Provided, however,* That a bovine animal vaccinated prior to June 26, 1975, in accordance with the existing definition of an official vaccinate as set forth in this part at the time of vaccination, shall be deemed to be an official vaccinate.

(m) *Herd.* Any group of animals of the same species maintained on common ground for any purpose, or two or more groups of animals (of the same species) under common ownership or supervision, geographically separated but which have an interchange or movement of animals without regard to health status.

(n) *Herd Depopulation.* Removal by slaughter or other means of destruction of all cattle, bison, or swine in a herd or from a specific premises or under common ownership prior to restocking such premises with new animals, except that steers and spayed heifers or barrows and gilts maintained for feeding purposes may be retained on the premises if the Veterinarian in Charge finds such retention to be compatible with eradication efforts. The Veterinarian in Charge may also permit removal of nonpregnant heifers, without payment of indemnity, to Quarantined Feedlots in lieu of immediate slaughter.

(o) *Registered cattle.* Cattle for which individual records of ancestry are recorded and maintained by a breed association whose purpose is the improvement of the bovine species, and for which individual registration certificates are issued and recorded by such breed association.

(p) *Registered swine.* Any breeding swine for which a certificate of pure breeding has been issued by a purebred swine association.

(q) *Inbred or hybrid swine.* Any breeding swine which are the progeny of two or more breeds of registered swine and which are maintained to produce inbred or hybrid swine, and for which records of ancestry exist through which such swine can be individually identified as progeny of said registered swine.

(r) *Permit.* An offical document for movement of animals under this Part issued by a Veterinary Services representative, state representative, or accredited veterinarian listing the disease status and identification of the animal, where consigned, cleaning and disinfecting requirements, and proof of slaughter certification.

(s) *Brucellosis reactor animal.* Any animal which has reacted to an official test for brucellosis as defined in the Uniform Methods and Rules, chapter I, part I-A and part II-G, or chapter II, part I-A and part II-G.[1]

(t) *Brucellosis exposed animal.* Any animal, except a brucellosis reactor animal, that is part of a herd known to be affected or that has been in contact with a brucellosis reactor animal in marketing or other channels for a period of 24 hours if such brucellosis reactor animal has aborted, calved, or farrowed within the past 30 days or has a vaginal or uterine discharge.

(u) *Herd known to be affected.* Any herd in which any animal has been classified as a brucellosis reactor and which has not been released from quarantine.

(v) *Animals.* Cattle, bison, and breeding swine.

(w) *Claimant.* A person who files a claim for indemnity under § 51.7 of this part for animals destroyed under this part.

(x) *Condemn.* The determination made by a Veterinary Services representative, State representative, or accredited veterinarian that animals for which indemnity is sought under this Part shall be destroyed.

(y) *State representative.* A veterinarian or other person regularly employed in livestock sanitary work of a State or a political subdivision thereof, and who is authorized by such State or political subdivision to perform the function involved under a cooperative agreement with the United States Department of Agriculture.

(z) *Dairy cattle.* A female bovine of a recognized dairy breed over 20 months of age, which has calved or is within 90 days of parturition and which is a member of a dairy herd used to produce milk for commercial use.

(aa) *Exposed female calf.* A female bovine less than 6 months of age which is nursed by a brucellosis reactor at the time such reactor is condemned.

(bb) *Official seal.* A serially numbered metal strip consisting of a self-locking device on one end and a slot on the other end, which forms a loop when the ends are engaged, which cannot be reused if opened, and is applied by a representative of the Veterinarian in Charge or the State animal health official.

(cc) *Registered breed association.* An association formed and perpetuated for the maintenance of records of purebreeding of animal species for a specific breed whose characteristics are set forth in Constitutions, By-Laws, and other rules of the association. The records maintained by such an association shall include an Official Herd Book or other recordkeeping format and Certificates of Registration or Recordation which identify an animal as a registered animal of that registered breed association. Known registered breed associations are: American Angus Association, American Beefalo Association, Inc., The American Black Maine-Anjou Association, American Brahman Breeders Association, American Brahmental Association, American Breed Association, Inc., American Chianina Association, American Dexter Cattle Association, American Galloway Breeders Association, American Gelbvieh Association, American Guernsey Cattle Club, American Hereford Association, American International Charolais Association, American International Marchigiana Society, American Jersey Cattle Club, American Maine-Anjou Association, American Milking Shorthorn Society, American Murray Grey Association, American Normande Association, American Pinzgauer Association, American Polled Hereford Association, American Red Brangus Association, American Red Poll Association, American Salers Association, American Scotch Highland Breeders Association, American Shorthorn Association, American Simmental Association, Inc., American Tarentaise Asssociation, Ankina Breeders, Inc., Ayrshire Breeders Association, Barzona Breed Association of America, Beefmaster Breeders Universal, Belted Galloway Society, Brahmanstein Breeders Association, Brown Swiss Beef International, Inc., Brown Swiss Cattle Breeders Association of U.S.A., Char-Swiss Breeders Association, Devon Cattle Association, Inc., Dutch Belted Cattle Association of America, Inc., Foundation Beefmaster Association, Galloway Cattle Society of America, Inc., Galloway Performance International, Holstein-Friesian Association of America, International Braford Association, International Brangus Breeders Association, Inc., International Maine-Anjou Association, Marky Cattle Association, Mid America RX$_3$ Cattle Company, National Beefmaster Association, North American Limousin Foundation, Pan American Zebu Association, Red and White Dairy Cattle Association, Red Angus Association of America, Red Poll Beef Breeders International, Red Poll Cattle Club of America, Santa Gertrudis Breeders International, South Devon Breed Society, Sussex Cattle Association of America, Texas Longhorn Breeders Association of America, and White Park Cattle Association of America.

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[1] Copies of the January 1975 Recommended Brucellosis Eradication Uniform Methods and Rules (APHIS 91-1) are available upon request from Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, Federal Building, Hyattsville, Md. 20782, and were filed as part of this original document.

(Secs. 3, 4, 5, 11, and 13, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; sec. 3, 33 Stat. 1265, as amended; sec. 3, 76 Stat. 130 (21 U.S.C. 111-113, 114, 114a-1, 120, 121, 125, 134b); 7 CFR 2.17, 2.51, and 371.2(d))

[42 FR 64336, Dec. 23, 1977, as amended at 43 FR 33678, Aug. 1, 1978; 44 FR 45604, Aug. 3, 1979; 45 FR 43678, June 27, 1980; 46 FR 13673, Feb. 23, 1981; 47 FR 53323, Nov. 26, 1982; 48 FR 57471, Dec. 30, 1983; 49 FR 20268, May 14, 1984; 49 FR 21041, May 18, 1984; 49 FR 33845, Aug. 27, 1984; 50 FR 11993, Mar. 27, 1985; 50 FR 19163, May 7, 1985; 50 FR 33514, Aug. 20, 1985]

§ 51.2 Cooperation with States.

The Deputy Administrator has been delegated the authority to cooperate with the proper State authorities in the eradication of brucellosis and to pay indemnities for the destruction of brucellosis-reactor animals or brucellosis-exposed animals.

§ 51.3 Payment to owners for animals destroyed.

(a) *Cattle and bison.* The Deputy Administrator may authorize[2] the payment of federal indemnity by the Department to any owner whose cattle or bison are destroyed as affected with brucellosis.

(1) *Brucellosis reactor cattle and bison.* The Deputy Administrator may authorize[2] the payment of Federal indemnity by the Department to owners whose cattle or bison are destroyed as brucellosis reactors. The indemnity shall not exceed $250 for any registered cattle or $50 for any nonregistered cattle or bison, except that, for nonregistered dairy cattle the indemnity shall not exceed $250, and except that in Alaska, Hawaii, Puerto Rico, and the Virgin Islands indemnity shall not exceed $250 for any registered cattle or $150 for any nonregistered

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[2] The Deputy Administrator shall authorize payment of Federal indemnity by the Department at the applicable maximum percent in § 51.3(a) (1) and (2) and the maximum per head rates in § 51.3(a)(3): (a) As long as sufficient funds appropriated by Congress appear to be available for this purpose for the remainder of the fiscal year; (b) In States or areas not under Federal quarantine; (c) In States requesting payment of Federal indemnity; and (d) In States not requesting a lower rate.

cattle or bison, except that, for nonregistered dairy cattle the indemnity shall not exceed $250. Prior to payment of indemnity, proof of destruction [3] shall be furnished to the veterinarian in charge.

(2) *Herd depopulation.* The Deputy Administrator may authorize [2] the payment of Federal Indemnity by the Department to any owner whose herd of cattle or bison is destroyed because of brucellosis. The indemnity shall not exceed $250 for any registered cattle or $50 for any nonregistered cattle or bison, except that, for nonregistered dairy cattle the indemnity shall not exceed $250, and except that, in Alaska, Hawaii, Puerto Rico, and the Virgin Islands indemnity shall not exceed $250 for any registered cattle or $150 for any nonregistered cattle or bison, except that, for nonregistered dairy cattle, the indemnity shall not exceed $250. Indemnity payment shall only be made for brucellosis-exposed cattle and bison or for cattle and bison from a herd known to be affected, and only when the Deputy Administrator determines that the destruction of all cattle and bison in the herd will contrib;ute to the brucellosis eradication program. Prior to payment of indemnity, proof of destruction [3] shall be furnished to the veterinarian in charge. Indemnity will be paid for reactor animals in accordance with § 51.3(a)(1).

(3) *Exposed female calves.* The Deputy Administrator may authorize [2] the payment of Federal indemnity to any owner whose *exposed female calf or calves* are destroyed because of brucellosis. The indemnity for such animals shall not exceed $50 per head. Indemnity payments shall be made only for exposed female calves and only when the Deputy Administrator determines that the destruction of such calves will contribute to the brucellosis eradication program. Prior to payment of indemnity, proof of destruction shall be furnished to the veterinarian in charge.

(b) *Swine*—(1) *Brucellosis reactor swine.* The Deputy Administrator may authorize [2] the payment of Federal indemnity by the Department to an owner whose breeding swine are destroyed as brucellosis reactors. The indemnity shall not exceed $25 per head for registered, inbred, or hybrid swine, or $10 per head for all other breeding swine. Prior to payment of indemnity, proof of destruction [3] shall be furnished to the Veterinarian in Charge.

(2) *Herd depopulation.* The Deputy Administrator may authorize [2] the payment of Federal indemnity by the Department to an owner whose herd of breeding swine is destroyed because of brucellosis. The indemnity shall not exceed $25 per head for registered, inbred, or hybrid swine, or $10 per head for all other breeding swine. Indemnity payment shall be made only for brucellosis exposed swine or for swine from a herd known to be affected and only when the Deputy Administrator determines that the destruction of all swine in the herd will contribute to the Brucellosis Eradication Program. Prior to payment of indemnity, proof of destruction [3] shall be furnished to the Veterinarian in Charge.

(3) *Exposed swine.* The Deputy Administrator may authorize [2] the payment of Federal indemnity by the Department to an owner whose breeding swine are destroyed because of brucellosis. The indemnity shall not exceed $25 per head for registered, inbred, or hybrid swine, or $10 per head for all other breeding swine. Indemnity payment shall be made only for such brucellosis exposed swine and only when the Deputy Administrator determines that the destruction of such swine will contribute to the Brucellosis Eradication Program. Prior to payment of indemnity, proof of destruction [3] shall

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[3] The Veterinarian in Charge shall accept any of the following documents as "proof of destruction": (a) A postmortem report; (b) A meat inspection certification of slaughter; (c) A written statement by a state representative, Veterinary Services representative, or accredited veterinarian attesting to the destruction of the animal; (d) A written, sworn statement by the owner or caretaker of the animal attesting to the destruction of the animal; (e) A permit (VS Form 1-27) consigning the animal from a farm or livestock market directly to a recognized slaughtering establishment as defined in § 78.1(dd) of this chapter; or (f) In unique situations where the documents listed above are not available, other similarly reliable forms of proof of destruction.

be furnished to the Veterinarian in Charge.

(Approved by the Office of Management and Budget under control number 0579-0067)

[42 FR 64336, Dec. 23, 1977, as amended at 45 FR 43679, June 27, 1980; 46 FR 13673, Feb. 23, 1981; 46 FR 57027, Nov. 20, 1981; 47 FR 53323, Nov. 26, 1982; 48 FR 57472, Dec. 30, 1983; 50 FR 11993, Mar. 27, 1985]

EFFECTIVE DATE NOTE: In § 51.3(b) (1)-(3), the second sentences were amended at 46 FR 57027, Nov. 20, 1981. At 46 FR 61641, Dec. 18, 1981, the effective date of the amendment was suspended until further notice. For the convenience of the user, the suspended amendment is set forth below.

§ 51.3 Payment to owners for animals destroyed.

* * * * *

2. In § 51.3(b), the second sentences in paragraphs (1), (2) and (3) are amended to read: The indemnity shall not exceed $50 per head for registered, inbred, and hybrid swine, and shall not exceed $25 per head for all other breeding swine.

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§ 51.4 Record of tests.

The claimant shall be responsible for providing information to Veterinary Services representative, State representative, or accredited veterinarian so that a complete test record may be made by such person on a Veterinary Services approved form for each herd known to be affected, including the reactor tag number of each brucellosis reactor animal and the registration name and number of each brucellosis reactor registered animal. A copy of the applicable test record shall be given to the owner of any such herd, and one copy of each such record shall be furnished to the appropriate State veterinarian's office by such person who completes the test record.

(Approved by the Office of Management and Budget under control number 0579-0067)

[42 FR 64336, Dec. 23, 1977, as amended at 48 FR 57472, Dec. 30, 1983]

§ 51.5 Identification of animals to be destroyed because of brucellosis.

(a) The claimant shall be responsible for insuring that any animal for which indemnity is claimed shall be identified in accordance with the provisions of this section within 15 days after having been classified as a reactor or for any other animal subject to this part within 15 days after having been condemned. The veterinarian in charge may extend the time limit to 30 days when a request for such extension is received by him prior to the expiration date of the original 15 day period allowed, and when he determines that the extension will not adversely affect the brucellosis eradication program; and except further, that the Deputy Administrator shall upon request in specific cases, extend the time limit beyond the 30-day period when unusual or unforeseen circumstances occur which prevent or hinder the identification of the animals within the 30-day period, such as, but not limited to, floods, storms, or other Acts of God which are beyond the control of the owner, or when identification is delayed due to requirements of another Federal Agency.

(b) Cattle and bison shall be identified by branding the letter "B" on the left jaw not less than 2 nor more than 3 inches high and by tagging with an approved metal tag bearing a serial number and description "U.S. Reactor" or a similar State reactor tag suitably attached to the left ear of each animal: *Provided, However,* That in lieu of branding with the letter "B" and tagging with an approved metal tag, reactors and exposed cattle and bison in herds scheduled for herd depopulation, may be identified by USDA approved backtags and either accompanied directly to slaughter by a Veterinary Services or State representative or moved directly to slaughter in vehicles closed with official seals. Such official seals may only be removed by a Veterinary Services representative, State representative, accredited veterinarian, or by other persons authorized for this purpose by a Veterinary Services representative.

(c) Swine shall be individually identified by tagging with a metal tag bearing a serial number and inscription "U.S. Reactor" or a similar State reactor tag or other identification approved by the Deputy Administrator, upon request in specific cases, attached to the left ear of each animal.

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[42 FR 64336, Dec. 23, 1977, as amended at 44 FR 45605, Aug. 3, 1979; 45 FR 24860, Apr. 11, 1980; 47 FR 53324, Nov. 26, 1982; 48 FR 57472, Dec. 30, 1983; 50 FR 11993, Mar. 27, 1985]

§ 51.6 Destruction of animals; time limit for destruction of animals.

(a) *Cattle.* The claimant shall be responsible for insuring that cattle subject to this part shall be sold under permit to a State or Federal slaughtering establishment approved by the Deputy Administrator for this purpose,[5] or to a stockyard approved by the Deputy Administrator for sale to such slaughtering establishment.[5]

(b) *Bison.* The claimant shall be responsible for insuring that bison subject to this part shall be sold under permit to a State or Federal slaughtering establishment approved by the Deputy Administrator for this purpose or to a stockyard approved by the Deputy Administrator for sale to such a slaughtering establishment, *Provided, However,* That the Deputy Administrator may approve such other bison slaughtering establishments as may be deemed necessary to accomplish destruction of bison subject to this part.

(c) *Swine.* The claimant shall be responsible for insuring that swine subject to this part shall be sold under permit to a slaughtering establishment where State or Federal meat inspection is available, or to a market approved by the State Animal Health Official, or to a market approved by the Deputy Administrator, for sale to such slaughtering establishment.[6]

(d) *Time limit for destruction of animals.* Payment of indemnity shall be made under this part only if the animals are destroyed within 15 days after the date of identification, pursuant to § 51.5 of the regulations in this part, except that the appropriate Veterinarian in Charge may extend the time limit to 30 days when request for such extension is received from the owner prior to the expiration date of the original 15-day period allowed, or when the animals were sold for slaughter prior to the expiration date of the original 15-day period, and when the Veterinarian in Charge determines that such extension will not adversely affect the Brucellosis Eradication Program; and except further, that the Deputy Administrator shall, upon request in specific cases, extend the time limit beyond the 30-day period when unusual and unforeseen circumstances occur which prevent or hinder the destruction of the animals within the 30-day period, such as, but not limited to, floods, storms, or other Acts of God which are beyond the control of the owner, or when destruction is delayed due to requirements of another Federal Agency.

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[42 FR 64336, Dec. 23, 1977, as amended at 45 FR 43680, June 27, 1980; 45 FR 86410, Dec. 31, 1980; 46 FR 5861, Jan. 21, 1981; 47 FR 53324, Nov. 26, 1982; 48 FR 57472, Dec. 30, 1983; 50 FR 11993, Mar. 27, 1985]

§ 51.7 Claims for indemnity.

(a) Claims for indemnity for animals destroyed because of brucellosis shall be presented on indemnity claim forms furnished by Veterinary Services on which the owner of the animals covered thereby shall certify that the animals are or are not subject to any mortgage as defined in this part. If the owner states there is a mortgage, the Veterinary Services indemnity claim form shall be signed by the owner and by each person holding a mortgage on the animals, consenting to the payment of any indemnity allowed to the person specified thereon. Payment will be made only if the claimant has submitted a complete indemnity claim form to, and such claim has been approved by the Veterinarian in Charge or by a Veterinary Services representative designated by him. On claims for indemnity made under the provisions of § 51.3, the Veterinarian in Charge or a Veterinary Services representative designated by him shall record on the Veterinary Services indemnity claim form the amount of Federal and State indemnity payments that appear to be due to the owner of the animals. The owner of the animals shall be furnished a copy of the completed Veterinary Services indemnity claim form. The Veterinarian in Charge or a Veterinary Services representative designated by him shall then forward the completed Veterinary Services indemnity claim form to the Deputy Administrator for further action on the claim. No charges for holding the animals on the farm pending slaughter or for trucking by the owner shall be so deducted or otherwise paid by the Department.

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[5] Slaughtering establishments and stockyards are approved by the Deputy Administrator in accordance with § 78.25 of the regulations.

[6] Markets are approved by the Deputy Administrator in accordance with the provisions in § 76.18 of the regulations.

(b) Cattle presented as registered shall be accompanied by their registration papers issued in the name of or transferred by the registered breed association to the name of the owner or shall be paid for as nonregistered cattle: *Provided, however,* That if the registration papers are not available because they have been sent to an association for transfer of ownership or if the cattle are less than 1 year old and unregistered, the Veterinarian in Charge may grant a reasonable time of not more than 30 days for the presentation of their registration papers: *Except that* the Deputy Administrator may extend the period an additional 30 days upon receipt of a request from the owner within the original 30-day period, when the owner can show to the satisfaction of the Deputy Administrator that the inability to produce the certificate within such 30-day period is due to circumstances beyond the owner's control.

(Approved by the Office of Management and Budget under control number 0579-0067)

[42 FR 64336, Dec. 23, 1977. Redesignated at 46 FR 13674, Feb. 23, 1981, and 47 FR 53324, Nov. 26, 1982, and amended at 47 FR 53324, Nov. 26, 1982; 48 FR 57472, Dec. 30, 1983; 50 FR 11993, Mar. 27, 1985]

§ 51.8 Disinfection of premises, conveyances, and materials.

All premises, including all structures, holding facilities, conveyances, and materials, contaminated because of occupation or use by brucellosis reactor or exposed animals shall be properly cleaned and disinfected with a disinfectant permitted by Veterinary Services in accordance with recommendations of the Veterinary Services or State representative within 15 days from the date reactors were removed from the premises, except that the appropriate Veterinarian in Charge may extend the time limit for disinfection to 30 days when request for such extension is received by him prior to the expiration date of the original 15-day period allowed, and when he determines that such extension will not adversely affect the Brucellosis Eradication Program; and except further, that the Deputy Administrator may, upon request in specific cases, extend the time limit beyond the 30-day period when unusual and unforeseen circumstances occur, such as but not limited to floods, storms, or other Acts of God, which are beyond the control of the owner, preventing or hindering the disinfection of premises, conveyances, and materials. Certain premises may be exempted from such cleaning and disinfecting requirements by approval of the appropriate Veterinarian in Charge on written recommendations by the Veterinary Services or State representative or when a written report by the Veterinary Services or State representative determines that there are no buildings, holding facilities, conveyances, or other materials on the premises that would require such cleaning and disinfection.

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[42 FR 64336, Dec. 23, 1977. Redesignated at 46 FR 13674, Feb. 23, 1981, and 47 FR 53324, Nov. 26, 1982; 48 FR 57472, Dec. 30, 1983; 50 FR 11993, Mar. 27, 1985]

§ 51.9 Claims not allowed.

Claims for compensation for animals destroyed because of brucellosis shall not be allowed if any of the following circumstances exist:

(a) If the claimant has failed to comply with any of the requirements of this part.

(b) If the existence of any such disease in the animal was determined as the result of an agglutination test applied in accordance with the Uniform Methods and Rules[1] by an accredited veterinarian and specific instructions for the administration of such test had not previously been issued to such veterinarian by the proper Veterinary Services and State authorities.

(c) If all cattle, bison, and swine eligible for testing in the claimant's herd have not been tested for brucellosis under Veterinary Services or State supervision.

(d) If the animals are barrows or gilts maintained for feeding purposes, or are spayed heifers or steers unless the steers are work oxen.

(e) If the animals are classified as reactors and are unofficial vaccinates, unless there is either a record of a negative official test made not less than 30 days following the date of unofficial vaccination or unless other Veterinary Services approved tests show the unofficial vaccinates are affected with virulent Brucella.

(f) If there is substantial evidence that the owner or his agent has in any way been responsible for any unlawful or improper attempt to obtain indemnity funds for such animal.

(g) If, at the time of test or condemnation, the animals belonged to or were upon the premises of any person to whom they had been sold for slaughter; shipped for slaugher, or delivered for slaughter.

(h) If any known brucellosis reactor animal remains in the herd, unless, in the opinion of the Veterinarian in Charge, a reasonable search has been made for the brucellosis reactor animal and the brucellosis reactor animal could not be found and removed.

(i) If the animals are brucellosis reactor animals which are slaughtered other than as part of a herd depopulation, and which are from a herd: (1) That was already classified as a "herd known to be affected" at the time the animals were identified as brucellosis reactor animals and (2) for which an approved action plan or approved individual herd plan (as defined in § 78.1 of this chapter) was not in effect at the time the claim was filed.

(Approved by the Office of Management and Budget under control number 0579-0067)

[42 FR 64336, Dec. 23, 1977. Redesignated at 46 FR 13674, Feb. 23, 1981, and 47 FR 53324, Nov. 26, 1982, and amended at 47 FR 53324, Nov. 26, 1982; 48 FR 57472, Dec. 30, 1983; 50 FR 11993, Mar. 27, 1985; 50 FR 47036, Nov. 14, 1985]

§ 51.10 Part 53 of this chapter not applicable.

No claim for indemnity for animals destroyed because of brucellosis shall hereafter be paid under the regulations contained in Part 53 of this chapter, but all such claims shall be presented and paid pursuant to and in compliance with regulations contained in this part.

[42 FR 64336, Dec. 23, 1977. Redesignated at 46 FR 13674, Feb. 23, 1981, and 47 FR 53324, Nov. 26, 1982; 50 FR 11993, Mar. 27, 1985]

PART 52—[RESERVED]

PART 53—FOOT-AND-MOUTH DISEASE, PLEUROPNEUMONIA, RINDERPEST, AND CERTAIN OTHER COMMUNICABLE DISEASES OF LIVESTOCK OR POULTRY

Sec.
53.1 Definitions.
53.2 Determination of existence of disease; agreements with States.
53.3 Appraisal of animals or materials.
53.4 Destruction of animals.
53.5 Disinfection or destruction of materials.
53.6 Disinfection of animals.
53.7 Disinfection of premises, conveyances, and materials.
53.8 Presentation of claims.
53.9 Mortgage against animals or materials.
53.10 Claims not allowed.

AUTHORITY: Sec. 3, 23 Stat. 32, as amended, sec. 2, 32, Stat. 792, as amended, sec. 11, 58 Stat. 734, as amended; 21 U.S.C. 114, 111, 114a, unless otherwise noted.

SOURCE: 28 FR 5935, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

CROSS REFERENCE: For non-applicability of Part 53 with respect to certain claims for indemnity, see § 51.10 of this chapter.

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[1] See footnote 1 to § 51.1.

§ 53.1 Definitions.

Words used in this part in the singular form shall be deemed to import the plural and vice versa, as the case may demand. Unless otherwise clearly indicated by the context, whenever the following words, names, or terms are used in the regulations in this part, they shall be construed, respectively, to mean:

(a) "Department" means the United States Department of Agriculture.

(b) "Secretary" means the Secretary of Agriculture of the United States, or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

(c) "Veterinary Services" means the Veterinary Services unit of the Animal and Plant Health Inspection Service, United States Department of Agriculture.

(d) "Veterinary Services employee" means any inspector or other individual employed in the division who is authorized by the Deputy Administrator, Veterinary Services to do any work or perform any duty in connection with the control and eradication of disease.

(e) "Inspector in charge" means an inspector of Veterinary Services who is designated by the Deputy Administrator, Veterinary Services to take charge of work in connection with the control and eradication of disease as defined in this section.

(f) "Disease" means foot-and-mouth disease, rinderpest, contagious pleuropneumonia, or any other communicable disease of livestock or poultry which in the opinion of the Secretary constitutes an emergency and threatens the livestock industry of the country; or any other communicable disease of livestock or poultry referred to in this paragraph:

(1) The communicable disease of poultry presently existing in the States of California, Florida, New Mexico, and Texas and diagnosed as exotic Newcastle-disease, at the time of slaughter, on the basis of clinical or laboratory evidence, by a Veterinary Services employee or representative of the particular State involved.

(2) Lethal avian influenza (a disease of poultry caused by any form of H5 influenza virus that has been determined by the Deputy Administrator, Veterinary Services, to have spread from the 1983 outbreak in poultry in Pennsylvania).

(g) "Materials" means parts of barns or other structures, straw, hay, and other feed for animals, farm products or equipment, clothing, and articles stored or contained in or adjacent to barns or other structures.

(h) "Person" means natural person, firm, partnership, corporation, company, society, and association, and every officer, agent, or employee thereof.

(i) "State" means each and every one of the States of the United States, the District of Columbia, and the Territories and possessions of the United States.

(j) "Mortgage" means any mortgage, lien or other security or beneficial interest held by any person other than the one claiming indemnity.

(k) "Animals"—Livestock, poultry, and all other members of the animal kingdom including birds whether domesticated or wild, but not including man.

(l) "Bird" means any member of the class aves other than poultry.

(m) "Poultry" means chickens, ducks, geese, swans, turkeys, pigeons, doves, pheasants, grouse, partridges, quail, guinea fowl, and pea fowl.

[28 FR 5935, June 13, 1963, as amended at 36 FR 25217, Dec. 30, 1971; 49 FR 3448, Jan. 27, 1984; 49 FR 26712, June 29, 1984]

§ 53.2 Determination of existence of disease; agreements with States.

(a) The Director of Division is hereby authorized to invite the proper State authorities to cooperate with the Department in the control and eradication of any disease within the meaning of § 53.1(f).

(b) Upon agreement of the authorities of the State to enforce quarantine restrictions and orders and directives properly issued in the control and eradication of such a disease, the Director of Division is hereby authorized to agree, on the part of the Department, to cooperate with the State in the control and eradication of the disease, and to pay 50 percent (and in the case of exotic Newcastle disease or lethal avian influenza, up to 100 percent) of the expenses of purchase, destruction and disposition of animals and materials required to be destroyed because of being contaminated by or exposed to such disease: *Provided, however,* That if the animals were exposed to such disease prior to or during interstate movement and are not eligible to receive indemnity from any State, the Department may pay up to 100 percent of the purchase, destruction, and disposition of animals and materials required to be destroyed: *Provided, further,* That the cooperative program for the purchase, destruction, and disposition of birds shall be limited to birds as referred to in § 82.2(a) of this chapter, and which are identified in documentation pursuant to Cooperative Agreements,[1] as constituting a threat to the poultry industry of the United States: *And provided further,* That the Secretary may authorize other arrangements for the payment of such expenses upon finding that an extraordinary emergency exists.

[37 FR 5689, Mar. 18, 1972, as amended at 49 FR 3448, Jan. 27, 1984; 49 FR 26712, June 29, 1984]

§ 53.3 Appraisal of animals or materials.

(a) Animals affected by or exposed to disease, and materials required to be destroyed because of being contaminated by or exposed to disease shall be appraised by a Veterinary Services employee and a representative of the State jointly, or, if the State authorities approve, by a Veterinary Services employee alone.

(b) The appraisal of animals shall be based on the fair market value and shall be determined by the meat, egg production, dairy or breeding value of such animals. Animals may be appraised in groups providing they are the same species and type and providing that where appraisal is by the head each animal in the group is the same value per head or where appraisal is by the pound each animal in the group is the same value per pound.

(c) Appraisals of animals shall be reported on forms furnished by Veterinary Services. Reports of appraisals shall show the number of animals of each species and the value per head or the weight and value by pound.

(d) Appraisals of materials shall be reported on forms furnished by Veterinary Services. Reports of appraisals of materials shall, when practicable, show the number, size or quantity, unit price, and total value of each kind of material appraised.

(21 U.S.C. 112, 113, 115, 117, 120, 121, 134b)

[28 FR 5935, June 13, 1963, as amended at 35 FR 13981, Sept. 3, 1970; 36 FR 25217, Dec. 30, 1971]

§ 53.4 Destruction of animals.

(a) Animals affected by or exposed to disease shall be killed promptly after appraisal and disposed of by burial or burning, unless otherwise specifically provided by the Deputy Administrator, Veterinary Services in extraordinary circumstances.

(b) The killing of animals and the burial, burning, or other disposal of carcasses of animals pursuant to the regulations in this part shall be supervised by a Veterinary Services employee who shall prepare and transmit to the Deputy Administrator, Veterinary Services a report identifying the animals and showing the disposition thereof.

§ 53.5 Disinfection or destruction of materials.

(a) In order to prevent the spread of disease, materials contaminated by or exposed to disease shall be disinfected: *Provided, however,* That in all cases in which the cost of disinfection would exceed the value of the materials or disinfection would be impracticable for any reason, the materials shall be destroyed, after appraisal as provided in § 53.3.

(b) The disinfection or destruction of materials under this section shall be under the supervision of a Veterinary Services employee who shall prepare and transmit to the Deputy Administrator, Veterinary Services a certificate identifying all materials which are destroyed, showing the disposition thereof.

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[1] Agreements between the Departments and the particular State involved relating to cooperative animal (including poultry) disease prevention, control, and eradication.

§ 53.6 Disinfection of animals.

Animals of species not susceptible to the disease for which a quarantine has been established, but which have been exposed to the disease, shall be disinfected when necessary by such methods as the Deputy Administrator, Veterinary Services shall prescribe from time to time.

§ 53.7 Disinfection of premises, conveyances, and materials.

All premises, including barns, corrals, stockyards and pens, and all cars, vessels, aircraft, and other conveyances, and the materials thereon, shall be cleaned and disinfected under supervision of a Veterinary Services employee whenever necessary for the control and eradication of disease. Expenses incurred in connection with such cleaning and disinfection shall be shared according to the agreement reached under § 53.2 with the State in which the work is done.

§ 53.8 Presentation of claims.

Claims for (a) compensation for the value of animals, (b) cost of burial, burning or other disposition of animals, (c) the value of material destroyed, and (d) the expenses of destruction, shall each be presented, through the inspector in charge, to Veterinary Services on separate vouchers in form approved by the Deputy Administrator, Veterinary Services.

§ 53.9 Mortgage against animals or materials.

When animals or materials have been destroyed pursuant to the requirements contained in this part, any claim for indemnity shall be presented on forms furnished by Veterinary Services on which the owner of the animals or materials shall certify that the animals or materials covered thereby, are, or are not, subject to any mortgage as defined in this part. If the owner states there is a mortgage, forms furnished by Veterinary Services shall be signed by the owner and by each person holding a mortgage on the animals or materials, consenting to the payment of any indemnity allowed to the person specified thereon.

§ 53.10 Claims not allowed.

(a) The Department will not allow claims arising under the terms of this part if the payee has not complied with all quarantine requirements.

(b) Expenses for the care and feeding of animals held for destruction will not be paid by the Department, unless the payment of such expense is specifically authorized or approved by the Deputy Administrator, Veterinary Services.

(c) The Department will not allow claims arising out of the destruction of animals or materials unless they shall have been appraised as prescribed in this part and the owners thereof shall have executed a written agreement to the appraisals.

(d) The Department will not allow claims arising out of the destruction of animals or materials which have been moved or handled by the owner thereof or its officer, employee, or agent, acting within the scope of his or its office, employment or agency, in violation of a law or regulation administered by the Secretary for the prevention of the introduction into or the dissemination within the United States of any communicable disease of livestock or poultry for which the animal or material was destroyed, or in violation of a law or regulation for the enforcement of which the Secretary enters or has entered into a cooperative agreement for the control and eradication of such disease.

[28 FR 5935, June 13, 1963, as amended at 45 FR 86411, Dec. 31, 1980]

PART 54—ANIMALS DESTROYED BECAUSE OF SCRAPIE

Sec.

54.1 Definitions.
54.2 Cooperation with States.
54.3 Appraisal of animals.
54.4 Time limit for slaughter.
54.5 Care and feeding of animals under quarantine; disposal of animals after slaughter.
54.6 Mortgage against animals.
54.7 Destruction and disposition of animals.
54.8 Payments to owners for animals destroyed.
54.9 Claims not allowed.

AUTHORITY: Sec. 3, 23 Stat. 32, as amended, sec. 2, 32 Stat. 792, as amended, sec. 11, 58 Stat. 734, as amended; 21 U.S.C. 114, 111, 114a, unless otherwise noted.

SOURCE: 28 FR 5936, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

§ 54.1 Definitions.

For the purpose of this part, the following words, names, and terms shall be construed, respectively, to mean:

Affected animal. An animal for which a diagnosis of scrapie has been made by a Veterinary Services representative or State representative.

Animal. A sheep or goat.

Bloodline animal. The dam of an affected animal and the dam's first generation progeny, the maternal granddam of an affected animal, the first generation progeny of an affected animal, and all succeeding generations of female progeny from female progeny of an affected female animal.

Department. The U.S. Department of Agriculture.

Deputy Administrator. The Deputy Administrator for Veterinary Services or any other Veterinary Services official to whom authority has been delegated or may hereafter be delegated to act in his stead.

Destroyed. Killed by slaughter or by such other means as may be authorized by the Deputy Administrator in an exceptional situation.

Mortgage. Any mortgage, lien, or other security or beneficial interest held by any person other than the one claiming indemnity.

Owner. A person, partnership, company, or corporation who has legal or rightful title to animals whether or not they are subject to a mortgage.

State. Any State or Territory or possession of the United States, the District of Columbia, or Puerto Rico.

State representative. A person employed in livestock sanitary work of a State or a political subdivision thereof, and who is authorized by such State or political subdivision to perform the function involved under a cooperative agreement with the U.S. Department of Agriculture.

Veterinary Services. The Veterinary Services unit of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

Veterinary Services representative. A person employed by Veterinary Services in animal health activities who is authorized by the Deputy Administrator to perform the function involved.

(Sec. 3, 23 Stat. 32, as amended; sec. 2, 32 Stat. 792, as amended; sec. 11, 58 Stat. 734, as amended (21 U.S.C. 111, 114, 114a, 134a-134h); 37 FR 28464, 28477, 38 FR 19141)

[43 FR 41184, Sept. 15, 1978, as amended at 48 FR 16236, Apr. 15, 1983; 48 FR 38206, Aug. 23, 1983]

§ 54.2 Cooperation with States.

Upon the determination by the Deputy Administrator, Veterinary Services of the existence of scrapie, he shall solicit the cooperation of the proper State or Territory authorities in the eradication of such disease.

§ 54.3 Appraisal of animals.

(a) Subject to the provisions of paragraph (b) of this section, affected animals and bloodline animals for which indemnity is to be paid under this part shall be appraised at their fair market value by an appraiser selected and employed by Veterinary Services in each of the Veterinary Services regions; except that, if the owner and State representative approve, such animals may be appraised by a Veterinary Services representative alone, or may be appraised jointly by a Veterinary Services representative and a State representative, *Provided,* That if the owner deems the appraisal of the Veterinary Services representative or of the joint Veterinary Services representative and State representative to be inadequate, the appraisal shall be made by an appraiser selected and employed by Veterinary Services in each of the Veterinary Services regions. Should the appraisal made by the appraiser employed by Veterinary Services be deemed inadequate by the owner, the owner may select and employ his own appraiser who shall appraise the animals and consult with the Veterinary Services appraiser and attempt to agree on the appraisal value. If the two appraisers do not agree on the appraisal value of the animals, the two appraisers shall select a third appraiser who will be employed by Veterinary Services. The three appraisers shall attempt to agree upon an appraisal value for the animals. Any appraisal agreed upon by these three appraisers will be final.

(b) Veterinary Services may decline to accept any appraisal that appears to it to be unreasonable or out of proportion to the value of similar animals of a like quality. Appraisals shall not exceed any limit set by the laws of the State or other agency which is cooperating with Veterinary Services in the payment of indemnity because of scrapie.

(Sec. 3, 23 Stat. 32, as amended; sec. 2, 32 Stat. 792, as amended; sec. 11, 58 Stat. 734, as amended (21 U.S.C. 111, 114, 114a, 134a-134h); 37 FR 28464, 28477, 38 FR 19141)

[28 FR 5936, June 13, 1963 as amended at 43 FR 41184, Sept. 15, 1978; 48 FR 16236, Apr. 15, 1983; 48 FR 38206, Aug. 23, 1983]

§ 54.4 Time limit for slaughter.

Animals slaughtered under this part shall be slaughtered within 15 days after the date of appraisal unless such time is specifically extended by the Deputy Administrator, Veterinary Services.

§ 54.5 Care and feeding of animals under quarantine; disposal of animals after slaughter.

Expenses for the care and feeding of animals held for destruction and the expense of destruction, burial, incineration, etc., and/or transportation and other expenses incidental to their slaughter will not be paid by the Department.

§ 54.6 Mortgage against animals.

When animals have been destroyed pursuant to the requirements contained in this part, any claim for indemnity shall be presented on forms furnished by Veterinary Services on which the owner of the animals shall certify that the animals covered thereby, are, or are not, subject to any mortgage as defined in this part. If the owner states there is a mortgage, forms furnished by Veterinary Services shall be signed by the owner and by each person holding a mortgage on the animals, consenting to the payment of any indemnity allowed to the person specified thereon.

§ 54.7 Destruction and disposition of animals.

(a) Indemnity for affected animals and bloodline animals destroyed under this part shall be paid only after Veterinary Services obtains the written agreement of the owner to accept from the United States compensation which shall be equal to two-thirds of the appraised value of each animal, not to exceed $300 per head.

(b) Affected animals and bloodline animals shall be destroyed on the premises where held, pastured, or penned at the time of appraisal; except that such animals may be moved for destruction to a location other than the premises where appraised when movement to such location is approved in advance by the State representative and Veterinary Services representative involved, and such animals are not to be processed for human food. The carcasses of the animals destroyed shall be disposed of by burial or incineration.

(c) The destruction and disposition of animals destroyed in accordance with this part shall be supervised by a Veterinary Services or State representative who shall prepare and transmit to the Deputy Administrator, Veterinary Services, a report identifying the animals and showing the disposition thereof.

(Sec. 3, 23 Stat. 32, as amended; sec. 2, 32 Stat. 792, as amended; sec. 11, 58 Stat. 734, as amended (21 U.S.C. 111, 114, 114a, 134a-134h); 37 FR 28464, 28477, 38 FR 19141)

[40 FR 40506, Sept. 3, 1975; 40 FR 42739, Sept. 16, 1975, as amended at 43 FR 41184, Sept. 15, 1978; 48 FR 16236, Apr. 15, 1983; 48 FR 38206, Aug. 23, 1983]

§ 54.8 Payments to owners for animals destroyed.

(a) Owners of affected animals and bloodline animals destroyed in accordance with this part shall be paid an indemnity by the United States equal to two-thirds of the appraised value of each animal so destroyed, not to exceed $300 per head.

(b) Veterinary Services may indemnify owners up to the limitations specified in this part whether or not the State participates in indemnity payment.

(c) Animals presented for appraisal as purebred shall be accompanied by their certificate of registry at the time of appraisal, or they shall be appraised as grades; except that, in the absence of such proof of purebreeding, the Deputy Administrator shall grant a reasonable time for the owner to obtain and present his certificate of registration to the Veterinary Services representative.

(Sec. 3, 23 Stat. 32, as amended; sec. 2, 32 Stat. 792, as amended; sec. 11, 58 Stat. 734, as amended (21 U.S.C. 111, 114, 114a, 134a-134h); 37 FR 28464, 28477, 38 FR 19141)

[43 FR 41185, Sept. 15, 1978, as amended at 48 FR 16236, Apr. 15, 1983; 48 FR 38206, Aug. 23, 1983]

§ 54.9 Claims not allowed.

(a) The Department will not allow claims arising out of the destruction of animals unless they have been previously appraised, and the owners thereof shall have executed agreements, in compliance with this part.

(b) The Department will not allow claims if the claimant has failed to comply with any of the Department regulations pertaining to scrapie including the necessary cleaning and disinfection of his premises and conveyances.

PART 55—[RESERVED]

PART 56—SWINE DESTROYED BECAUSE OF HOG CHOLERA

Sec.

56.1 Definitions.
56.2 Cooperation with States.
56.3 Appraisal of swine.
56.4 Care and feeding of swine under quarantine; disposal after slaughter.
56.5 Mortgages against swine.
56.6 Destruction of swine.
56.7 Payments to owners for swine destroyed.
56.8 Claims not allowed.

AUTHORITY: Secs. 3-5, 23 Stat. 32, as amended, sec. 2, 32 Stat. 792, as amended, sec. 3, 33 Stat. 1265, as amended, sec. 11, 58 Stat. 734, as amended; 21 U.S.C. 111-114a, 120, 125.

SOURCE: 28 FR 9915, Sept. 12, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

§ 56.1 Definitions.

For the purpose of this part, the following words, names, and terms shall be construed, respectively, to mean:

(a) "The Department" means the United States Department of Agriculture.

(b) "Veterinary Services" means the Veterinary Services unit of the Animal and Plant Health Inspection Service, United States Department of Agriculture.

(c) "Destroyed" means condemned under State or Federal authority and destroyed by slaughter or by dealth otherwise.

(d) "Hog Cholera" means the contagious, infectious, and communicable disease of swine commonly known as hog cholera.

(e) "Mortgage" means any mortgage, lien, or other security or beneficial interest held by any person other than the one claiming indemnity.

(f) "State" means each and every one of the States of the United States, the District of Columbia, Puerto Rico and the Territories and possessions of the United States.

(g) *Purebred swine.* Any breeding swine upon which a certificate of pure breeding has been issued by a purebred swine association.

(h) *Inbred or hybrid swine.* Any breeding swine which are the progeny of two or more breeds of foundation stock for which records of ancestry are available and which are maintained for breeding purposes as a part of a formal breeding program to produce inbred or hybrid swine, and for which records of ancestry exist through which such swine can be identified as progeny of said foundation stock.

(i) *Breeding swine.* Grade female swine which are maintained for breeding purposes as a part of a formal breeding program.

[28 FR 9915, Sept. 12, 1963, as amended at 33 FR 10005, July 12, 1968; 34 FR 14881, Sept. 27, 1969; 35 FR 16314, Oct. 17, 1970; 40 FR 30099, July 17, 1975]

§ 56.2 Cooperation with States.

Upon determination by the Deputy Administrator, Veterinary Services of the existence of hog cholera, and upon agreement of the authorities of the State to enforce quarantine restrictions and orders and directives properly issued in the control and eradication of hog cholera, he is authorized to cooperate with the proper State authorities in the eradication of such disease.

§ 56.3 Appraisal of swine.

Swine affected with or exposed to hog cholera which are to be destroyed and indemnities paid therefor under this part shall be appraised at their actual value for meat, feeding or breeding purposes at the place and time of appraisal, except that in the case of grade animals only females shall be eligible for appraisal based on breeding value and that no such appraisal shall exceed three times the animals' meat or feeding value. Appraisal shall be made by a Veterinary Services or State representative or jointly. The record of appraisal shall be signed by the appraiser, or appraisers, and by the owner certifying his acceptance of the appraisal. Swine may be appraised in groups providing they are the same type and providing that where appraisal is by the head each animal in the group is the same value per head or where appraisal is by the pound each animal in the group is the same value per pound. Swine presented for appraisal as purebred swine shall be accompanied by their certificate of pure breeding; swine presented for appraisal as inbred or hybrid swine shall be accompanied by their certificate of registration. Certificates of pure breeding for purebred swine or certificates of registration for inbred or hybrid swine shall be presented at the time of appraisal or such swine will be appraised as grades: *Provided, however,* That in the absence of such certificate of pure breeding; or certificate of registration for inbred or hybrid swine the Deputy Administrator, Veterinary Services may grant a reasonable time for the presentation of the certificate of pure breeding or registration to the appraiser.

[33 FR 10005, July 12, 1968]

§ 56.4 Care and feeding of swine under quarantine; disposal after slaughter.

The Department may pay up to 100 percent of expenses for the purchase, destruction, and disposition of animals and materials required to be destroyed because of being contaminated by or exposed to hog cholera. The amount of the claim which may be paid for destruction, burial, incineration, rendering, or otherwise disposing of swine infected with or exposed to hog cholera shall be determined by a Veterinary Services or State representative or jointly. The record of such claim shall be signed by a Veterinary Services or State representative or jointly and by the owner certifying his acceptance of the amount claimed. The Department will not pay expenses for the care and feeding of swine held for destruction except as specifically approved by the Deputy Administrator, and in the case of approval, such expenses for care and feeding of such swine shall be deducted from the appraised value of the swine and indemnity payments may be made to the limit specified in § 56.7.

[38 FR 16842, June 27, 1973, as amended at 40 FR 30099, July 17, 1975]

§ 56.5 Mortgages against swine.

Any indemnity claim for swine destroyed pursuant to the requirements contained in this part shall be presented on forms furnished by Veterinary Services on which the owner of the swine shall certify that the swine covered thereby, are, or are not, subject to any mortgage as defined in this part. If the owner states there is a mortgage, forms furnished by the Veterinary Services shall be signed by the owner and by each person holding a mortgage on the swine, consenting to the payment of any indemnity allowed to the person specified thereon.

§ 56.6 Destruction of swine.

(a) Swine affected with or exposed to hog cholera which are to be destroyed and indemnities paid therefor under this part shall be destroyed promptly after appraisal and disposed of through a method of salvage approved by the Deputy Administrator, Veterinary Services or by burial or burning.

(b) The destruction of swine and the burial, burning, or other disposal of carcasses of swine pursuant to the regulations in this part shall be supervised by a Department or State employee who shall prepare and transmit to the Deputy Administrator, Veterinary Services a report identifying the swine and showing the disposition thereof.

§ 56.7 Payment to owners for swine destroyed.

(a) Owners of swine destroyed in accordance with this part in any State may be paid an indemnity not to exceed 100 percent of the appraised value of the swine destroyed. An indemnity may be paid not to exceed $360 per head for purebred, inbred, or hybrid swine and for breeding swine, or $180 per head for all other swine.

(b) If the Department has paid the expenses of care and feeding of swine held for destruction in accordance with § 56.4, such expenses shall be deducted from the appraised value of the swine, and the difference between the appraised value and such expenses shall be used as the net appraised value for computing indemnity claims.

(21 U.S.C. 114g, 115, 117, 121, 123, 124, 126, 134a–h)

[28 FR 9915, Sept. 12, 1963, as amended at 40 FR 30099, July 17, 1975; 41 FR 8944, Mar. 2, 1976]

§ 56.8 Claims not allowed.

(a) The Department will not allow claims arising out of the destruction of swine unless they have been previously appraised in compliance with this part.

(b) The Department will not allow claims if the claimant has failed to comply with any of the Department regulations or quarantine regulations of the cooperating State pertaining to hog cholera, and the cleaning and disinfection of his premises or conveyances as deemed necessary by Deputy Administrator, Veterinary Services to destroy hog cholera virus.

(c) The Department will not allow claims if there is substantial evidence that the owner or his agent has in any way been responsible for any attempt unlawfully or improperly to obtain indemnity funds for such swine.

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

PART 70—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER CERTAIN ACTS

Subpart A—General

Sec.
70.1 Scope and applicability of rules of practice.

Subpart B—Supplemental Rules of Practice

70.10 Stipulations.

AUTHORITY: Secs. 4-7, 23 Stat. 32, as amended; secs. 2 and 3, 32 Stat. 792, as amended; secs. 1, 3, 4, and 6, 33 Stat. 1264, 1265, as amended; sec. 11, 58 Stat. 734, as amended; sec. 2, 65 Stat. 693, as amended; secs. 3 and 4, 76 Stat. 130, sec. 6, 76 Stat. 131, as amended; sec. 11, 76 Stat. 132; 21 U.S.C. 111, 112, 114a, 114a-1, 115, 117, 120, 122, 123, 125-127, 134b, 134c, 134e, 134f; 7 CFR 2.17, 2.51, 371.2(d).

SOURCE: 48 FR 30094, June 30, 1983, unless otherwise noted.

Subpart A—General

§ 70.1 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the Department of Agriculture promulgated in Subpart H of Part 1, Subtitle A, Title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings under the following statutory provisions:

Act of May 29, 1884, commonly known as the Animal Industry Act, Section 7, as amended (21 U.S.C. 117),

Act of February 2, 1903, commonly known as the Cattle Contagious Diseases Act of 1903, Section 3, as amended (21 U.S.C. 122),

Act of March 3, 1905, Section 6, as amended (21 U.S.C. 127),

Act of July 2, 1962, Section 6(a), as amended (21 U.S.C. 134e).

In addition, the Supplemental Rules of Practice set forth in Subpart B of this part shall be applicable to such proceedings.

Subpart B—Supplemental Rules of Practice

§ 70.10 Stipulations.

(a) At any time prior to the issuance of a complaint seeking a civil penalty under any of the Acts listed in § 70.1, the Administrator, in his discretion, may enter into a stipulation with any person in which:

(1) The Administrator or the Administrator's delegate gives notice of an apparent violation of the Act, or the regulations issued thereunder, by such person and affords such person an opportunity for a hearing regarding the matter as provided by the Act;

(2) Such person expressly waives hearing and agrees to pay a specified penalty within a designated time; and

(3) The Administrator agrees to accept the penalty in settlement of the particular matter involved if the penalty is paid within the designated time.

(b) If the penalty is not paid within the time designated in such a stipulation, the amount of the stipulated penalty shall not be relevant in any respect to the penalty which may be assessed after issuance of a complaint.

PART 71—GENERAL PROVISIONS

Sec.
71.1 Definitions.
71.2 Secretary to issue rule governing quarantine and interstate movement of diseased animals, including poultry.
71.3 Interstate movement of diseased animals and poultry generally prohibited.
71.4 Maintenance of certain facilities and premises in a sanitary condition required; cleaning and disinfection, when required; animals classed as "exposed."
71.5 Unsanitary railroad cars, trucks, boats, aircraft or other means of conveyance; interstate movement restricted.
71.6 Carrier responsible for cleaning and disinfecting of railroad cars, trucks, boats, aircraft or other means of conveyance.
71.7 Means of conveyance, facilities and premises; methods of cleaning and disinfecting.

Sec.

71.10 Substances or materials allowed as permitted disinfectants.

71.11 Cresylic disinfectant as permitted disinfectant; specifications.

71.12 Sodium orthophenylphenate as permitted disinfectant for premises infected with tuberculosis.

71.13 Inspection of shipments in transit by Veterinary Services inspector.

71.14 Slaughter of poultry or other animals to prevent spread of disease; ascertainment of value and compensation.

71.15 Movement from quarantined to free area and shipment therefrom; conditions under which permitted.

71.16 Inspection and certification of poultry or other animals for interstate movement.

71.17 Interstate movement of dead poultry or other animals prohibited in same car with live poultry or other animals.

71.18 Individual identification of certain cattle 2 years of age or over for movement in interstate commerce.

AUTHORITY: 21 U.S.C. 111-113, 114a, 114a-1, 115-117, 120-126, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 28 FR 5937, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

§ 71.1 Definitions.

For the purposes of this subchapter the following words, phrases, names, and terms shall be construed, respectively, to mean:

Accredited herd. One officially declared by Veterinary Services and the State as free from tuberculosis and for which a certificate has been issued evidencing that fact.

Department. The United States Department of Agriculture.

Designated dipping station. A point mutually agreed upon by the Division and the State livestock sanitary authorities, where proper dipping and yarding facilities are provided, at which cattle of the area of that State quarantined for splenetic, southern, or Texas fever in cattle may be dipped, inspected, and certified for interstate movement.

Free area. The States, Territories, or the District of Columbia or portions thereof not quarantined by the Secretary of Agriculture for the specific contagious, infectious, or communicable animal disease mentioned in each part.

Interstate. From one State into or through any other State.

Moved (movement) in interstate commerce. Moved from the point of origin of the interstate movement to the animals' final destination, such as a slaughtering establishment or a farm for breeding or raising, and including any temporary stops for any purpose prior to movement to final destination, such as stops at a stockyard or dealer premises for feed, water, rest, or sale.

Official Brand Inspection Agency. The duly constituted body elected, appointed, or delegated or granted authority by a State or governmental subdivision thereof, to administer laws, regulations, ordinances or rules pertaining to the brand identification of livestock.

Official brand inspection certificate. A certificate issued by an official brand inspection agency in any State in which such certificates are required for movement of livestock.

Person. Any individual, corporation, company, association, firm, partnership, society, or joint stock company, or other legal entity.

Quarantined area. The States, Territories, or the District of Columbia or portions thereof quarantined by the Secretary of Agriculture for the specific contagious, infectious, or communicable animal disease mentioned in each part.

Recognized slaughtering center. Any point where slaughtering facilities are provided and to which animals are regularly shipped and slaughtered.

State. Any State, Territory, the District of Columbia, or Puerto Rico.

Stockers and feeders. Animals intended for stock or feeding purposes.

Tick infested. Infested with the ticks Boophilus annulatus (Margaropus annulatus), Boophilus microplus, or Rhipicephalus evertsi evertsi.

Veterinary Services. The Veterinary Services unit of the Animal and Plant Health Inspection Service.

Veterinary Services inspector. An inspector of Veterinary Services.

[28 FR 5937, June 13, 1963, as amended at 29 FR 14489, Oct. 22, 1964; 35 FR 14197, Sept. 9, 1970; 38 FR 18011, July 6, 1973; 50 FR 45987, Nov. 6, 1985]

§ 71.2 Secretary to issue rule governing quarantine and interstate movement of diseased animals, including poultry.

When the Secretary of Agriculture shall determine the fact that poultry or other animals in any State, Territory, or the District of Columbia are affected with any contagious, infectious, or communicable disease of livestock or poultry for which, in his opinion, a quarantine should be established or that other basis for a quarantine exists, notice will be given of that fact, and a rule will be issued accordingly, placing in quarantine such State, Territory, or the District of Columbia, or specified portion thereof. This rule will either absolutely forbid the interstate movement of the quarantined animals from the quarantined area or will indicate the regulations under which interstate movements may be made.

[34 FR 15641, Oct. 9, 1969]

§ 71.3 Interstate movement of diseased animals and poultry generally prohibited.

(a) Animals or poultry affected with any of the following diseases, which are endemic to the United States: Equine piroplasmosis, bovine piroplasmosis or splenetic fever, scabies in cattle, hog cholera, acute swine erysipelas, tuberculosis, paratuberculosis, brucellosis, scrapie, bluetongue, anthrax, psittacosis or ornithosis, and Newcastle disease, or any other communicable disease which is endemic to the United States, or which are cattle fever tick infested, shall not be moved interstate.

(b) Animals or poultry affected with any of the following diseases, not known to exist in the United States: foot-and-mouth disease, rinderpest, African swine fever, Teschen disease, contagious bovine pleuropneumonia, European fowl pest, dourine, vesicular exanthema, screwworms and glanders, scabies in sheep or any other communicable foreign disease not known to exist in the United States, shall not be moved interstate.

(c) Notwithstanding the provisions of paragraphs (a) and (b) of this section: (1) Domestic animals which have reacted to a test recognized by the Secretary of Agriculture for brucellosis, or paratuberculosis, which are not affected with any other disease referred to in this section and are not tick infested, may be moved interstate in accordance with the provisions of Subpart B of Part 78 of this subchapter in the case of brucellosis reactors and with the provisions of Part 80 of this subchapter in the case of paratuberculosis reactors; and (2) cattle which have reacted to the tuberculin test, which are not affected with any other disease referred to in this section and are not tick infested, may be moved interstate in accordance with the provisions of § 77.8 of this subchapter.

(d) Notwithstanding the provisions of paragraphs (a) and (b) of this section, livestock which is found to be diseased may be moved interstate in accordance with paragraphs (d) (1) through (6) of this section: *Provided*, That such livestock is not tick infested or affected with any disease referred to in this section other than the diseases named in this paragraph: *And provided further*, That such livestock is accompanied by a certificate, issued by a Veterinary Services or State inspector or accredited veterinarian stating the destination of the animals; the purpose for which they are to be moved; the number of animals covered by the certificate; the point from which the animals are moved interstate; and the name and address of the owner or shipper.

(1) Livestock affected with one or more of the following diseases may be moved interstate for immediate slaughter to a slaughtering establishment where State or Federal meat inspection is maintained; Actinomycosis, actinobacillosis, anaplasmosis, atrophic rhinitis, contagious ecthyma, foot rot, infectious keratitis, ram epididymitis, ringworm, swine influenza, arthritis (simple lesions only), and shipping fever.

(2) Cattle with slight unopened cases of actinomycosis or actinobacillosis (or both) may be moved interstate to a feed lot in the State of destination: *Provided*, That such cattle are not affected with any other disease named in this paragraph.

(3) Sheep affected with or exposed to contagious ecthyma may be moved interstate to a feed lot located in a State the laws, rules, or regulations of which require that such sheep be segregated or quarantined under a permit from an official of such State: *Provided*, That such sheep are not affected with any other disease named in this paragraph.

(4) Livestock affected with one or more of the following diseases may be moved interstate for any purpose to a State the laws, rules, or regulations of which require that such livestock be segregated or quarantined under a permit from the appropriate livestock sanitary official of such State: actinomycosis, actinobacillosis, contagious ecthyma, foot rot, and shipping fever: *Provided*, That such livestock is not affected with any other disease named in this paragraph.

(5) Livestock affected with infectious keratitis or ringworm (or both) may be moved interstate for any purpose if treated under the supervision of a Veterinary Services or State inspector or an accredited veterinarian prior to movement: *Provided*, That such livestock is not affected with any other disease named in this paragraph. Livestock affected with infectious keratitis or ringworm (or both) and also with another disease named in this paragraph may be moved interstate only under the applicable provisions of paragraphs (d) (1) through (4) of this section after being so treated for infectious keratitis or ringworm (or both). Such livestock will be subject to further treatment at destination, if required.

(6) Other Movements. The Deputy Administrator, Veterinary Services may provide for the movement, not otherwise provided for in this paragraph, of animals affected with the diseases named in paragraph (d)(1) of this section, under such conditions as he may prescribe to prevent the spread of disease. The Deputy Administrator, Veterinary Services will promptly notify the appropriate livestock sanitary officials of the States involved of any such action.

(e) Notwithstanding the provisions of paragraphs (a) and (b) of this section, the Deputy Administrator, Veterinary Services in specific cases and under such conditions as he may prescribe to prevent the dissemination of disease may provide for the interstate movement of individual animals affected with contagious, infectious, or communicable disease to a designated diagnostic or research facility when accompanied by a permit from the appropriate livestock sanitary official in the State of destination: *Provided*, That animals so moved shall be maintained in quarantine at such designated facility until freed of disease as determined by tests recognized by the Department, until natural death, or until disposal by euthanasia.

(f) Before offering cattle or other livestock or poultry for interstate transportation, transporting them interstate, or introducing them into any stockyards or upon routes of traffic for interstate transportation, all persons, companies, or corporations are required to exercise reasonable diligence to ascertain whether such animals or poultry are affected with any contagious, infectious, or communicable disease, or have been exposed to the contagion or infection of any such disease by contact with other animals or poultry so diseased or by location in pens, cars, or other vehicles, or upon premises that have contained animals or poultry so diseased.

(Secs. 4-7, 23 Stat., as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264 and 1265, as amended; (21 U.S.C. 111-113, 115, 117, 120, 123-126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141)

[28 FR 5937, June 13, 1963, as amended at 28 FR 13929, Dec. 21, 1963; 30 FR 8327, June 30, 1965; 30 FR 13573, Oct. 26, 1965; 32 FR 7583, May 24, 1967; 35 FR 7249, May 8, 1970; 38 FR 18457, July 11, 1973; 46 FR 59528, Dec. 7, 1981; 47 FR 7826, Feb. 23, 1982; 47 FR 56983, Dec. 22, 1982; 48 FR 37921, Aug. 22, 1983]

§ 71.4 Maintenance of certain facilities and premises in a sanitary condition required; cleaning and disinfection, when required; animals classed as "exposed."

(a) Yards, pens, chutes, alleys, and other facilities and premises which are used in connection with the interstate movement of livestock or poultry shall be maintained by the person in possession of the facilities and premises in a clean and sanitary condition, in accordance with good animal husbandry practices, and shall be subject to inspection by a Veterinary Services or State inspector. When such inspector determines that such facilities or premises are not in such clean and sanitary condition and gives written notice of his determination to such person, the facilities and premises shall be cleaned and disinfected in accordance with §§ 71.7 and 71.10 through 71.12 by such person under the supervision of such an inspector or an accredited veterinarian before such premises are again used for livestock or poultry.

(b) Yards, pens, chutes, alleys, and other facilities and premises which have contained interstate shipments of cattle, sheep, swine, poultry, or other animals affected with, or carrying the infection of, any contagious, infectious, or communicable disease of livestock or poultry other than slight unopened cases of actinomycosis or actinobacillosis (or both), bovine foot rot, atrophic rhinitis, ram epididymitis, ringworm, infectious keratitis, and arthritis (simple lesions only), shall be cleaned and disinfected under the supervision of a Veterinary Services or State inspector or an accredited veterinarian in accordance with §§ 71.7 and 71.10 through 71.12 before such premises are again used for animals, and any poultry or other animals unloaded into such yards or premises before they have been so cleaned and disinfected shall thereafter be classed as "exposed" within the meaning of the regulations in this subchapter and shall not be moved interstate except in compliance with the provisions of such regulations applicable to "exposed" animals.

[34 FR 15641, Oct. 9, 1969]

§ 71.5 Unsanitary railroad cars, trucks, boats, aircraft or other means of conveyance; interstate movement restricted.

No person who receives notice from a Veterinary Services inspector that a railroad car, truck, boat, aircraft or other means of conveyance owned or operated by such person is not in a clean and sanitary condition in accordance with good animal husbandry practices, shall thereafter use such means of conveyance in connection with the interstate movement of livestock or poultry, or move said means of conveyance interstate, until it has been cleaned and disinfected under the supervision of a Veterinary Services or State inspector or an accredited veterinarian in accordance with §§ 71.7 and 71.10 through 71.12.

[34 FR 15641, Oct. 9, 1969]

§ 71.6 Carrier responsible for cleaning and disinfecting of railroad cars, trucks, boats, aircraft or other means of conveyance.

(a) Railroad cars, trucks, boats, aircraft, and other means of conveyance which have been used in the interstate transportation of cattle, sheep, swine, poultry, or other animals affected with, or carrying the infection of, any contagious, infectious, or communicable disease of livestock or poultry, other than slight unopened cases of actinomycosis or actinobacillosis (or both), atrophic rhinitis, bovine foot rot, brucellosis, ram epididymitis, ringworm, infectious keratitis, and arthritis (simple lesions only), shall be cleaned and disinfected under Veterinary Services supervision in accordance with §§ 71.7 and 71.10 through 71.12 at the point where the animals are unloaded and the final carrier shall be responsible for such cleaning and disinfecting: *Provided,* That when Veterinary Services supervision is not available at such point, the means of conveyance may be cleaned and disinfected under the supervision of a State inspector or an accredited veterinarian.

(b) No railroad car, truck, boat, aircraft or other means of conveyance from which poultry or other animals affected with an infectious, contagious or communicable disease of livestock or poultry, other than those specified in § 71.4(b), have been unloaded shall thereafter be used in connection with the interstate movement of animals, including poultry, or be moved interstate until it has been cleaned and disinfected by the final carrier under the supervision of a Veterinary Services or State inspector or an accredited veterinarian in accordance with §§ 71.7 and 71.10 through 71.12.

(c) If Veterinary Services supervision or other supervision as required by paragraph (a) or (b) of this section or proper cleaning and disinfecting facilities are not available at the point where the animals are unloaded, upon permission first received from the Veterinary Services, the means of conveyance may be forwarded empty to a point at which such supervision and facilities are available, and there be cleaned and disinfected under supervision in accordance with §§ 71.7 and 71.10 through 71.12.

[34 FR 15641, Oct. 9, 1969, as amended at 37 FR 25337, Nov. 30, 1972; 39 FR 4465, Feb. 4, 1974]

§ 71.7 Means of conveyance, facilities and premises; methods of cleaning and disinfecting.

(a) Railroad cars, trucks, aircraft, or other means of conveyance, except boats, required by the regulations in this subchapter to be cleaned and disinfected shall be treated in the following manner: Remove all litter and manure from all portions of the conveyance, including any external ledges and framework; clean the exterior and interior of the conveyance; and saturate the entire interior surface, including the inner surface of the doors of the conveyance, with a permitted disinfectant specified in §§ 71.10 through 71.12.

(b) Boats required by the regulations in this subchapter to be cleaned and disinfected shall be treated in the following manner: Remove all litter and manure from the decks and stalls, and all other parts of the boat occupied or traversed by any poultry or other animals and from the portable chutes or other appliances or fixtures used in loading and unloading the animals, and saturate with a permitted disinfectant the entire surface of the deck, stalls, or other parts of the boat occupied or traversed by any animals or with which they may come in contact or which have contained litter or manure.

(c) Yards, pens, chutes, and alleys required by the regulations in this subchapter to be disinfected shall be treated in the following manner: Empty all troughs, racks, or other feeding or watering appliances; remove all litter and manure from the floors, posts, or other parts; and saturate the entire surface of the fencing, troughs, chutes, floors, walls, and other parts with a permitted disinfectant specified in §§ 71.10 through 71.12.

[34 FR 15642, Oct. 9, 1969]

§ 71.10 Substances or materials allowed as permitted disinfectants.

(a) The substances permitted for use in disinfecting cars, boats, other vehicles, and premises are as follows:

(1) "Cresylic disinfectant" in the proportion of at least 4 fluid ounces to 1 gallon of water.

(2) Liquefied phenol (U.S.P. strength 87 percent phenol) in the proportion of at least 6 fluid ounces to 1 gallon of water.

(3) Chlorinated lime (U.S.P. strength, 30 percent available chlorine) in the proportion of 1 pound to 3 gallons of water.

(4) Sodium hydroxide (Lye) prepared in a fresh solution in the proportion of not less than 1 pound avoirdupois of sodium hydroxide of not less than 95 percent purity to 6 gallons of water, or one 13½ ounce can to 5 gallons of water. Due to the extreme caustic nature of sodium hydroxide solution, precautionary measures such as the wearing of rubber gloves, boots, raincoat, and goggles should be observed. An acid solution such as vinegar shall be kept readily available in case any of the sodium hydroxide solution should come in contact with the body.

(5) Disinfectants which are registered under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135 et seq.), with tuberculocidal claims, as disinfectants for general use, may be used for the purpose of this part in accordance with directions on the labels accepted in connection with their registration. However, disinfectants which fall in this category are not permitted for use in outbreaks of foreign animal diseases unless in specific cases such use is approved in advance by the Deputy Administrator, Veterinary Services.

(b) The use of "cresylic disinfectant" is permitted subject to the following conditions:

(1) The manufacturer thereof shall have obtained specific permission from Veterinary Services for the use of his products in official disinfection. To obtain such permission manufacturers shall first submit a sample of at least 8 ounces for examination, together with a statement of the formula employed and a guaranty that the product will be maintained of a quality uniform with the sample submitted.

(2) To prevent confusion, the product of each manufacturer and distributor shall bear a distinctive trade name or brand, together with the name of the manufacturer or distributor.

(3) The product shall at all times conform to specifications for composition and performance issued by the Deputy Administrator, Veterinary Services.

[28 FR 5937, June 13, 1963, as amended at 32 FR 19157, Dec. 20, 1967; 37 FR 8864, May 2, 1972; 37 FR 9460, May 11, 1972]

§ 71.11 Cresylic disinfectant as permitted disinfectant; specifications.

The following specifications will be employed for determining the suitability of cresylic disinfectant for use under the provisions of § 71.10(b)(3):

(a) The product shall remain a uniform liquid when held at 0° C. (32° F.) for 3 hours (chill test).

(b) The product shall dissolve completely in 30 parts of distilled water at 25° C. (77° F.) within 2 minutes (solution-rate test), producing a solution entirely free from globules and not more than faintly opalescent (solubility-degree test).

(c) The product shall contain not more than 25 percent of inert ingredients (water and glycerin), not more excess alkali than the equivalent of 0.5 percent of sodium hydroxide, and not less than 21 percent of soap exclusive of water, glycerin, and excess alkali.

(d) The product shall contain not less than 50 percent and not more than 53 percent of total phenols. It shall contain less than 5 percent of benzophenol (C_6H_5OH).

(e) The methods of determining compliance with the specifications in paragraphs (a) to (d) of this section will be those described in United States Department of Agriculture Bulletin 1308, Chemical and Physical Methods for the Control of Saponified Cresol Solutions, so far as they are applicable.

(f) Any suitable glyceride, fat acid, or resin acid may be used in preparing the soap, but not all are suitable nor are all grades of a single product equally suitable, Also various grades of commercial cresylic acid differ in suitability. Therefore, manufacturers are cautioned to prepare a trial laboratory batch from every set of ingredients and to prove its conformity with paragraphs (a) and (b) of this section, before proceeding with manufacture on a factory scale.

§ 71.12 Sodium orthophenylphenate as permitted disinfectant for premises infected with tuberculosis.

(a) A permitted brand of sodium orthophenylphenate in a proportion of at least one pound to 12 gallons of water is permitted in tuberculosis eradication work for disinfecting infected premises following the removal of cattle that reacted to the tuberculin test.

(b) It is absolutely necessary that the solution be applied at a temperature of 60° F. or over. Whenever the temperature of the building to be disinfected is below 60° F., as indicated by a wall thermometer, the solution shall be heated to 120° F. and higher in very cold weather, to insure effective disinfection.

§ 71.13 Inspection of shipments in transit by Veterinary Services inspector.

All persons and corporations having control of the interstate transportation of livestock or poultry shall, when directed by a Veterinary Services inspector so to do, stop the same in transit for inspection, and if any of such poultry or other animals are found upon such inspection to be infected with any contagious, infectious, or communicable disease or to have been exposed to such infection, the person or corporation having control of the transportation of such poultry or other animals shall, upon receipt of an order from a Veterinary Services inspector so to do, cease the carriage, transportation, or moving of such poultry or other animals unless such carriage, transportation, or moving can be accomplished in accordance with the regulations in this subchapter governing the interstate movement of poultry or other animals infected with or which have been exposed to the infection of such disease, and in all cases after the discovery of such infection or exposure thereto such poultry or other animals shall be handled in accordance with such regulations.

[28 FR 5937, June 13, 1963, as amended at 34 FR 15642, Oct. 9, 1969]

§ 71.14 Slaughter of poultry or other animals to prevent spread of disease; ascertainment of value and compensation.

When, in order to prevent the spread of any contagious, infectious, or communicable disease, it becomes necessary to slaughter any diseased or exposed animals, including poultry, and the purchase of such animals, including poultry, by the United States is authorized by law and an appropriation is available therefor, the value of the animals, including poultry shall be ascertained and compensation made therefor in accordance with the orders or regulations of the Secretary of Agriculture.

[28 FR 5937, June 13, 1963, as amended at 34 FR 15642, Oct. 9, 1969]

§ 71.15 Movement from quarantined to free area and shipment therefrom; conditions under which permitted.

No livestock or poultry shall be shipped, trailed, driven, or hauled in private conveyance from the quarantined area in any State, Territory, or the District of Columbia to the free area in the same State, Territory, or the District of Columbia and subsequently delivered to a transportation company for shipment or moved to any other State, Territory, or the District of Columbia without complying with all Federal and State regulations pertaining to such movements.

[28 FR 5937, June 13, 1963, as amended at 34 FR 15642, Oct. 9, 1969]

§ 71.16 Inspection and certification of poultry or other animals for interstate movement.

(a) *Assistance and facilities.* When poultry or other animals are to be inspected and certified by a Veterinary Services inspector, assistance and proper facilities for restraining them shall be provided in order that a careful inspection may be made, and the inspector while making the inspection shall not be interfered with in any manner; otherwise inspection will be immediately discontinued.

(b) *Certificates and other statements to accompany shipments.* Whenever inspection or treatment and the issuance of a certificate, statement, test chart, or other writing showing the performance of such inspection or treatment and the result thereof is required by any of the regulations in this subchapter as a condition precedent to the movement interstate of any poultry or other animal or class of poultry or other animals, or any poultry or other animal or class of poultry or other animals is so required to be accompanied in interstate movement by such certificate, statement, test chart, or other writing, no such poultry or other animal or poultry or other animals shall be moved interstate unless and until the following requirements are also complied with:

(1) In the case of such movement by a common carrier issuing waybills or other form or forms of billing covering the movement, the said certificate, statement, test chart, or other writing shall be delivered to such carrier at the time the poultry or other animal or poultry or other animals are delivered for shipment, and shall become the property of the carrier, and be by such carrier attached to the billing covering the transportation of such poultry or other animal or poultry or other animals, and accompany such billing to destination, and be filed with such billing for future reference.

(2) In case of such movement otherwise than by common carrier issuing waybills or other form or forms of billing, the said certificate, statement, test chart, or other writing shall accompany the poultry or other animal or poultry or other animals to destina-

tion and be delivered to the consignees, or, in case the consignor and consignee is the same person, to the first purchaser purchasing during or after such movement in interstate commerce, or to the person to whom the poultry or other animal or poultry or other animals are delivered.

[28 FR 5937, June 13, 1963, as amended at 34 FR 15642, Oct. 9, 1969]

§ 71.17 Interstate movement of dead poultry or other animals prohibited in same car with live poultry or other animals.

No dead poultry or other animals shall be offered or accepted for transportation or transported in the same car with live poultry or other animals from the original point of shipment in any State or Territory or the District of Columbia to or through any other State, Territory, or the District of Columbia.

[28 FR 5937, June 13, 1963, as amended at 34 FR 15642, Oct. 9, 1969]

§ 71.18 Individual identification of certain cattle 2 years of age or over for movement in interstate commerce.

(a) No cattle 2 years of age or over, except steers and sprayed heifers and except cattle of any age which are being moved in interstate commerce without change of ownership to another premises belonging to the same owner during the course of normal ranching operations, as provided in § 78.9 (a), (b)(3)(iv), (c)(3)(iv), and (d)(3)(vii) of this Subchapter C, shall be moved in interstate commerce other than in accordance with the requirements of this section. Any movement in interstate commerce of any cattle shall also comply with the other applicable provisions in this part and other parts of this subchapter.

(1) When permitted under such other provisions, cattle subject to this section:

(i) May be moved in interstate commerce from any point to any destination, if such cattle, when moved in interstate commerce, are identified by a Department-approved backtag[1] affixed a few inches from the midline and just behind the shoulder of the animal, or by such other means approved by the Deputy Administrator, Veterinary Services, upon request in specific cases, and if such cattle when moved interstate are accompanied by a statement signed by the owner or shipper of the cattle, or other document[2] stating: (*a*) The point from which the animals are moved interstate; (*b*) the destination of the animals; (*c*) the number of animals covered by the statement, or other document; (*d*) the name and address of the owner or shipper, and (*e*) the identifying numbers of the backtags or other approved identification applied: *Provided*, That identification numbers are not required to be recorded on such statement or document for cattle moved from a stockyard posted under the provisions of the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 181 *et seq.*),[3] directly to a slaughtering establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or slaughtering establishment specifically approved under § 78.16(b) of this subchapter; or

(ii) May be moved in interstate commerce only from a farm, ranch, or feedlot to a slaughtering establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or slaughtering establishment specifically approved under § 78.16(b) of this subchapter; or to a stockyard posted under the provisions of the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 181 *et seq.*), for sale and shipment to such a slaughtering establishment, if such cattle are identified upon arrival at such slaughtering establishment or stockyard by the application of Department-approved backtags or by other approved identification as prescribed in subdivision (i), and when moved interstate, are accompanied by a statement signed by the owner or shipper of the cattle, or other document[2] stating: (*a*) The point from which the animals are moved interstate; (*b*) the destination of the animals; (*c*) the number of animals covered by the statement or other document; and (*d*) the name and address of the owner or shipper: *Provided,* That the application of backtags is not required if such cattle are moved in interstate commerce to a federally inspected or specifically approved slaughtering establishment and if, when moved in interstate commerce, such cattle are identified by a brand registered with an official brand inspection agency and are accompanied by an official brand inspection certificate: *And provided, further,* That the application of backtags is not required when such cattle are moved in interstate commerce to a federally inspected or specifically approved slaughtering establishment, which maintains records of ownership of cattle by slaughter lot number;[4] or

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[1] Department-approved backtags are available at slaughtering establishments operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), at stockyards and slaughtering establishments specifically approved under § 78.16(b) of this subchapter, and from Federal and State inspectors as defined in § 78.1 of this subchapter. Information with respect to the federally inspected slaughtering establishments, specifically approved slaughtering establishments, and specifically approved stockyards may be obtained as indicated in §§ 78.14 and 78.15 of this subchapter.

[2] Other document means a shipping permit, an official health certificate, an official brand inspection certificate, a bill of lading, a waybill, or an invoice on which is listed the required information.

[3] Posted stockyards are designated by posting notice at such stockyards and by publication in the FEDERAL REGISTER. Information concerning posted stockyards may also be obtained from the Washington office or the area offices of the Packers and Stockyards Administration.

(iii) May be moved in interstate commerce for any purpose other than slaughter if such cattle, when moved in interstate commerce, are identified by Animal and Plant Health Inspection Service-approved eartags in lieu of backtags, and are accompanied when moved interstate by an owner's statement or other document[2] stating: (*a*) The point from which the animals are moved interstate, (*b*) the destination of the animals, (*c*) the number of animals covered by the statement or other document, (*d*) the identifying numbers of the eartags, and (*e*) the name and address of the owner or shipper: *Provided,* That identification by eartag is not required if such animals are registered purebred animals which are moved in interstate commerce for any purpose other than slaughter and are identified in a manner acceptable to the appropriate breed association for registration purposes; or are identified by a brand registered with an official brand inspection agency and are accompanied by an official brand inspection certificate as prescribed in paragraph (a)(1)(ii) of this section.

(2) The owner's or shipper's statement or other document[2] or registered purebred identification required by this section for cattle moved under paragraph (a)(1) (i) or (ii) of this section shall be delivered to the management of the stockyard or slaughtering establishment at the time of delivery of the cattle;[5] and documents accompanying animals moved under paragraph (a)(1)(iii) of this section for breeding or dairy purposes shall be delivered to the consignee. All such documents shall be made available for inspection on request by a State or Federal inspector or an accredited veterinarian, as defined in § 78.1, at any time within the year from the date of such delivery.

(3) Each person who ships, transports, or otherwise causes the cattle to be moved in interstate commerce is responsible for the identification of the cattle as required by this section.

(4) No person shall remove or tamper with or cause the removal of or tampering with a backtag, eartag, brand, or other identification device required to be on cattle pursuant to this section while such cattle are being moved in interstate commerce, except

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[4] It is the responsibility of the person who causes the interstate movement to determine whether the establishment maintains such records. As evidence that the establishment does maintain such records such person should obtain a statement to that effect from the management of the establishment and retain it for a period of five years from the date of shipment.

[5] The backtag or other identification numbers should be included on the receiving document of the stockyard or establishment for all such cattle identified by backtags or other identification after arrival at such stockyard or establishment.

at the time of slaughter, or as may be authorized by the Deputy Administrator, Veterinary Services, upon request in specific cases and under such conditions as the Deputy Administrator, Veterinary Services, may impose to ensure continuing identification.

[38 FR 22768, Aug. 24, 1973, as amended at 47 FR 55656, Dec. 13, 1982; 50 FR 45987, Nov. 6, 1985]

PART 72—TEXAS (SPLENETIC) FEVER IN CATTLE

Sec.

72.1 Ticks [Boophilus annulatus (Margaropus annulatus), Boophilus microplus, or Rhipicephalus evertsi evertsi]; interstate movement of infested or exposed animals prohibited.
72.2 Splenetic or tick fever in cattle in Texas, the Virgin Islands of the United States and vectors of said disease in the Northern Mariana Islands, the Commonwealth of Puerto Rico and the Island of Guam: Restrictions on movement of cattle.
72.3 Areas quarantined in the Virgin Islands of the United States, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the Island of Guam.
72.4 [Reserved]
72.5 Area quarantined in Texas.
72.6 Interstate movement of cattle from quarantined areas not eradicating ticks.
72.7 Interstate movement of cattle from cooperating States.
72.8 Interstate movement of cattle from free premises upon inspection and certification by Veterinary Services inspector.
72.9 Interstate movements of cattle; inspection and certification by Veterinary Services inspector required.
72.10 Inspected or dipped and certified cattle subject to restrictions of State of destination.
72.11 Quarantined area; cattle considered infested; requirements for placing in noninfectious pens or premises.
72.12 Cattle; exposure to tick infestation after treatment or inspection prohibited.
72.13 Permitted dips and procedures.
72.14 [Reserved]
72.15 Owners assume responsibility; must execute agreement prior to dipping or treatment waiving all claims against United States.
72.16 Designated dipping stations to be approved by the Deputy Administrator, Veterinary Services on recommendations of State authorities; facilities.

Sec.

72.17 Unloading noninfected cattle for rest, feed, and water only, permitted in authorized pens for such purpose.
72.18 Movement interstate; specification by the Deputy Administrator, Veterinary Services of treatment required when dipping facilities unavailable.
72.19 Interstate shipments and use of pine straw, grass, litter from quarantined area; prohibited until disinfected.
72.20 Exhibition of noninfected cattle in the quarantined area; restrictions under which permitted.
72.21 Animals infested with or exposed to ticks subject to same restrictions as cattle.
72.22 Cars, vehicles and premises; cleaning and treatment after containing infested or exposed animals.
72.23 Cars or other vehicles having carried infested or exposed cattle in quarantined area shall be cleaned and treated.
72.24 Litter and manure from carriers and premises of tick-infested animals; destruction or treating required.
72.25 Dipping methods.

AUTHORITY: 21 U.S.C. 111-113, 115, 117, 120, 121, 123-126, 134b, and 134f; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 28 FR 5940, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

§ 72.1 Ticks [Boophilus annulatus (Margaropus annulatus), Boophilus microplus, or Rhipicephalus evertsi evertsi]; interstate movement of infested or exposed animals prohibited.

No animals infested with ticks [Boophilus annulatus (Margaropus annulatus), Boophilus microplus, or Rhipicephalus evertsi evertsi] or exposed to tick infestation shall be shipped, trailed, driven, or otherwise moved interstate for any purpose, except as provided in this part.

§ 72.2 Splenetic or tick fever in cattle in Texas, the Virgin Islands of the United States and vectors of said disease in the Northern Mariana Islands, the Commonwealth of Puerto Rico and the Island of Guam: Restrictions on movement of cattle.

Notice is hereby given that the contagious, infectious, and communicable disease known as splenetic or tick fever exists in cattle in portions of the State of Texas and the Virgin Islands of the United States. Notice is also hereby given that ticks which are vectors of said disease exist in the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the Island of Guam. Therefore, portions of the State of Texas, the Virgin Islands of the United States, the Northern Mariana Islands, the Commonwealth of Puerto Rico and the Island of Guam are hereby quarantined as provided in §§ 72.3 and 72.5, and the movement of cattle therefrom into any other State or Territory or the District of Columbia shall be made only in accordance with the provisions of this part and Part 71 of this chapter.

[43 FR 60864, Dec. 29, 1978]

§ 72.3 Areas quarantined in the Virgin Islands of the United States, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the Island of Guam.

The entire Territories of the Virgin Islands of the United States and the Island of Guam, the Northern Mariana Islands, and the Commonwealth of Puerto Rico are quarantined.

[43 FR 60864, Dec. 29, 1978]

§ 72.4 [Reserved]

§ 72.5 Area quarantined in Texas.

The following portions of the specified counties in Texas are quarantined:

(a) That portion of *Val Verde County* lying generally southwest of a line beginning at the point on the south bank of the Devils River where the Amistad Dam Compound east fence intersects the water line and following this east fence of the compound in a southerly direction to the southeast corner of the Amistad Dam Compound, approximately 1¾ miles; thence, following the meanderings of this compound fence in a southwesterly direction to where it intersects the east right-of-way fence of the old railroad, approximately 3¼ miles; thence, following the old railroad right-of-way fence in a southeasterly direction to its intersection with the right-of-way fence of the present Southern Pacific Railroad, approximately 3⅛ miles; thence, following Southern Pacific Railroad in a southeasterly direction to a point directly north across a gravel road from the northeast corner of the Slover Field, approximately 5¾ miles; thence, south across this gravel road to the northeast corner of the Slover Field and following the meanderings of the east fence of the Slover Field in a southwesterly direction to where it intersects the northeast corner of the Woodson Field #1, approximately ⅛ mile; thence, following the meanderings of Woodson Field #1 east fence in a southwesterly direction to the southwest corner of the same, approximately ¼ mile to the north fence of the Payne Pasture; thence, following the north fence of the Payne Pasture in a westerly direction to the southwest corner of the same, approximately 100 yards; thence, following the west fence of the Payne Pasture in a southeasterly direction across Cienegas Creek to its junction with Kite Road, approximately 100 yards; thence, following Kite Road in a southerly direction to where it intersects Garza Lane, approximately 3/10 mile; thence, following Garza Lane in a westerly direction to a corner, approximately ⅛ mile; thence, following Garza Lane in a southeasterly direction to where it intersects U.S. Highway 277 Spur, approximately 1⅛ miles; thence, following U.S. Highway 277 Spur in a southeasterly direction to its intersection with Hudson Drive, approximately ½ mile; thence, following Hudson Drive in a southeasterly direction to where it joins Rio Grande Drive, formerly called Silo Field Road, approximately 9/10 mile; thence, following the west fence of Rio Grande Drive in a southeasterly direction to where it joins the east fence of the Rudy Mota Vega,[1] approximately 4/10 mile; thence, following the east fence of the Rudy Mota Vega in a southerly direction to where it joins the San Felipe Creek, approximately 3/10 mile; thence, following San Felipe Creek in an easterly direction to where it joins the W. L. Moody Rancho Rio Grande north fence of the Leroyce Pasture, approximately 1 3/10 miles; thence, following the meanderings of the Leroyce Pasture north fence in an easterly direction to a corner where it intersects the west right-of-way fence of U.S. Highway 277 being the east fence of the Rancho Rio Grande, approximately 3$\frac{8}{10}$ miles; thence, following the Rancho Rio Grande east fence (on the west side of Highway 277) in a southeasterly direction to where it intersects the Val Verde-Kinney County Line, approximately 9$\frac{8}{10}$ miles

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[1] Vega is a flat lowland area.

(b) That portion of *Kinney County* lying generally southwest of a line beginning at the point where the Rancho Rio Grande east fence intersects the Val Verde-Kinney County Line; thence, following the meanderings of the Rancho Rio Grande east fence in a southeasterly direction to where it intersects the Kinney-Maverick County Line, approximately 14 miles.

(c) That portion of *Maverick County* lying generally southeasterly of a line beginning at the point where the Rancho Rio Grande east fence intersects the Kinney-Maverick County Line; thence, following the Rancho Rio Grande east fence in a southeasterly direction to where it joins the southeast corner of the Rancho Rio Grande four section pasture, approximately 2$\frac{7}{10}$ miles; thence, following the south fence of the Rancho Rio Grande four section pasture in a westerly direction to a point where it intersects the Maverick County Water District main canal, approximately 1$\frac{5}{10}$ miles; thence, following the Maverick County Water District main canal in a southeasterly direction to where it intersects the west right-of-way fence of U.S. Highway 277, approximately 2$\frac{8}{10}$ miles; thence, following the right-of-way fence of U.S. Highway 277 in a southerly direction to where it intersects Maverick County Water District Lateral #2, approximately ½ mile; thence, following the Maverick County Water District Lateral #2 in a southerly direction to where it intersects the north fence of the Calley property, approximately 5¼ miles; thence, east along the north fence of the Calley property to a corner, approximately 200 yards; thence, following the east fence of the Calley property in a southerly direction to the northeast corner of the Hal Bowles Ranch, approximately ⅝ mile; thence, following the east fence of the Hal Bowles Ranch in a southeasterly direction to where it intersects the north fence of the Lehman Brothers Ranch, approximately ¾ mile; thence, following the Lehman north fence in a southeasterly direction to a drainage canal, approximately ⅛ mile; thence, following the drainage canal in a southerly direction to the north fence of the Las Vegas Ranch, approximately ⅞ mile; thence, following the meanderings of the Las Vegas Ranch fence in a southeasterly direction to the northeast corner of the same, approximately 1 mile; thence, following the meanderings of the east fence of the Las Vegas Ranch in a southerly direction to where it intersects the Alex Ritchie north fence, approximately 3½ miles; thence, along the north fence of the Alex Ritchie Farm in an easterly direction to where it intersects the Maverick County Water District main canal, approximately ⅜ mile; thence, following the meanderings of the Maverick County Water District main canal in a southerly direction to where it intersects the C.P. & L. Power Plant Road, approximately 3½ miles; thence, following the C.P. & L. Power Plant Road in an easterly direction to where it intersects the west fence of the Beer Joint Trap,[2] approximately 1⅜ miles; thence, following the west fence of the Beer Joint Trap in a southerly direction to the southwest corner of the same, approximately ⅝ mile; thence, following the meanderings of the south fence of the Beer Joint Trap in an easterly direction to where it intersects the west right-of-way fence of U.S. Highway 277, approximately ¾ mile; thence, following U.S. Highway 277 in a southerly direction into the City of Eagle Pass, Texas, and following the meanderings of U.S. Highway 277 in a southerly direction to its intersection with Church Street, approximately 8½ miles; thence, following Church Street in a westerly direction to its intersection with Commercial Street, approximately $\frac{5}{10}$ mile; thence, following Commercial Street in a southerly direction to its intersection with Garrison Street, approximately 7/10 mile; thence, following Garrison Street in an easterly direction to its intersection with Adams Street, approximately 9/10 mile; thence, following the meanderings of Adams Street in a southerly direction to where it becomes Industrial Park Road, approximately 1 mile; thence, following the meanderings of Industrial Park Road to where it intersects Brown Street, approximately 1½ miles; thence, following Brown Street in an easterly direction to the intersection of Farm Road 1021, approximately ½ mile; thence, following Farm Road 1021 in a southeasterly direction to the intersection of Farm Road 1021 and Farm Road 2366; thence, following Farm Road 2366 in a southwesterly direction to an intersection of Farm Road 2366 and a paved county road, approximately 1½ miles; thence, continuing along a paved county road in a southwesterly direction to a cattle guard at the eastmost corner of the Loma Linda Ranch double fence, approximately 1¼ miles; thence, following the same double fence in a westerly direction to a corner, approximately ⅝ mile; thence, following the same double fence in a northerly direction to a corner, approximately ¾ mile; thence, following the same double fence in a westerly direction to the northwest corner of the Loma Linda Ranch, approximately ⅞ mile; thence, following the meanderings of the same double fence in a southerly direction to the north fence of the W.D. Ranch, approximately 1⅛ miles; thence, following the same double fence along the north property line of the W.D. Ranch in a westerly direction to the northwest corner of the same, approximately ⅝ mile; thence, following the same double fence along the meanderings of the Rio Grande River in a southeasterly direction to the northwest corner of the El Indio Land Company Ranch, approximately 1 mile; thence, following the meanderings of the same double fence parallel to the Rio Grande River in a southeasterly direction to where it intersects the west fence of the Kiesling Rio Ledo Farm, approximately 4 miles; thence, following the same double fence in a southeasterly direction to where it joins the west fence of the Stone Ranch Upper Pasture, approximately 1¼ miles; thence, following the meanderings of the Stone Ranch Upper Pasture west double fence in a northerly direction to a corner, approximately ½ mile; thence, following the same double fence along the north property line of the Stone Ranch Upper Pasture in a northeasterly direction to where it intersects the Maverick County quarantine fence at El Indio vat, approximately ¾ mile; thence, following the meanderings of the Maverick County quarantine line fence in a southerly direction to the northwest corner of the Kiesling Lake Pasture, approximately 10¾ miles; thence, along the Kiesling Lake Pasture double fence in a southeasterly direction to where it intersects the north fence of the Dick Swartz Ranch Mansfield Pasture, approximately 1¾ miles; thence, following the meanderings of a double fence in a southeasterly direction paralleling the Rio Grande River to the south fence of the Swartz Ranch Mansfield Pasture, approximately 5 miles; thence, following the meanderings of the south fence of the Swartz Ranch Mansfield Pasture in a northeasterly direction to the Eagle Pass-Laredo River Road which will be called the Mines Road from this point south, approximately 4 miles; thence, following the Mines Road in a southeasterly direction to the Maverick-Webb County Line, approximately 14 miles.

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[2] A trap is an area in which animals may be trapped.

(d) That portion of *Webb County* lying generally southwest of a line beginning at the point where the Maverick-Webb County Line intersects the Mines Road and following this road in a southeasterly direction to where it intersects the north double fence of the Las Minas Ranch, approximately 43½ miles; thence, following the north double fence of the Las Minas Ranch in a westerly direction to the northwest corner of the same, approximately 1¼ miles; thence, following the west double fence of the Las Minas Ranch in a southerly direction to the southwest corner of the same, approximately 3¾ miles; thence, following the south double fence of the Las Minas Ranch in an easterly direction to where it intersects the Mines Road, approximately 2⅛ miles; thence, following the Mines Road in a southeasterly direction to its intersection with Del Mar Boulevard and Interstate Highway 35, approximately 16 9/10 miles; thence, following Interstate Highway 35 in a southerly direction to its intersection with Matamoros Street (U.S. Highway 83), approximately 4 1/10 miles; thence, following Matamoros Street (U.S. Highway 83) in an easterly direction approximately 1 mile to where Matamoros Street (U.S. Highway 83) becomes Guadalupe Street; thence, following Guadalupe Street in an easterly direction approximately 1½ miles to where U.S. Highway 83 turns in a southerly direction; thence, following U.S. Highway 83 in a southerly direction, approximately 12 3/10 miles to where it intersects the north double fence of the H.B. Zachary Ranch; thence, following the meanderings of this double fence in a westerly direction to the northwest corner of the same double fence, approximately 5 6/10 miles; thence, following the meanderings of the H.B. Zachary west double fence in a southeasterly direction to a corner, approximately 4½ miles; thence, following the same fence in an easterly direction to a corner, approximately ⅝ mile; thence, following the same fence in a southerly direction to a corner, approximately ⅜ mile; thence, following the H.B. Zachary Ranch south double fence in an easterly direction to where it intersects U.S. Highway 83 at the Webb-Zapata County Line, approximately 4 miles.

(e) That portion of *Zapata County* lying generally southwest of a line beginning at the point where U.S. Highway 83 intersects the Webb-Zapata County Line and following U.S. Highway 83 in a southerly direction to where it intersects the Martinez Windmill Trap north fence, approximately 3/10 mile; thence, east along the north fence of the Martinez Windmill Trap to the northeast corner of same, approximately 9/10 mile; thence, following the east fence of the Martinez Windmill Trap in a southerly direction to the southeast corner of same, approximately 1/10 mile; thence, along the south fence of the Martinez Windmill Trap in a westerly direction to where it intersects U.S. Highway 83, approximately 3/10 mile; thence, following U.S. Highway 83 in a southerly direction to where it intersects the Juan Vidaurri heirs' pasture north fence, approximately 2 9/10 miles; thence, following the Juan Vidaurri heirs' pasture north fence in an easterly direction to the northeast corner of same, approximately 1 9/10 miles; thence, following the meanderings of the Juan Vidaurri heirs' pasture east fence in a southerly direction to where it intersects the north fence of the Dye Farm, approximately 2 6/10 miles; thence, following the north fence of the Dye Farm in a westerly direction to where it intersects U.S. Highway 83, approximately ⅛ mile; thence, following U.S. Highway 83 in a southerly direction to where it intersects the Zapata City Limits fence, approximately 25 miles; thence, along the Zapata City Limits fence in a westerly direction to a corner, approximately 1/16 mile; thence, following the meanderings of the Zapata City Limits fence in a southeasterly direction to the southeast corner of the Eddie Bravo Trap, approximately 2 9/10 miles; thence, following the south fence of the Eddie Bravo Trap in a westerly direction to its intersection with the water line of Falcon Lake, approximately 9/10 mile; thence, following the meanderings of the water line of Falcon Lake in a southeasterly direction to its intersection with U.S. Highway 83, approximately 1 3/10 miles; thence, following U.S. Highway 83 in a southerly direction to where it intersects the Zapata-Starr County Line, approximately 23⅛ miles.

(f) That portion of *Starr County* lying generally south of a line beginning at the point where U.S. Highway 83 intersects the Zapata-Starr County Line and following a fence along the Zapata-Starr County Line in a southwesterly direction to where it intersects the east fence of the Falcon State Park, approximately 3¾ miles; thence, following the east fence of the Falcon State Park in a southeasterly direction to a corner, approximately 1 mile; thence, following the same fence in an easterly direction to a corner, approximately 100 yards; thence following the same fence in a southerly direction to a corner, approximately 100 yards; thence, following the same fence in an easterly direction to a cattle guard at the entrance of Falcon State Park at Old U.S. Highway 83, approximately 4/10 mile; thence, across Park Road 46 at the entrance to Falcon State Park on Old U.S. Highway 83 and following the park enclosure fence in a southerly direction to a corner, approximately 100 yards; thence, following Falcon State Park fence in a westerly direction to a corner, approximately 4/10 mile; thence, following the same fence in a southerly direction to where it intersects the north fence of the IBWC Compound, approximately 4/10 mile; thence, following the IBWC Compound north fence in an easterly direction to its intersection with Old U.S. Highway 83, approximately 4/10 mile; thence, following Old U.S. Highway 83, also known as F.M. Road 2098, south and southeast to its junction with the present U.S. Highway 83, approximately 4¼ miles; thence, following U.S. Highway 83 in a southeasterly direction to the south fence of the M. Ramirez pasture at the north city limits of Roma, Texas, approximately 9½ miles; thence, following the south fence of the M. Ramirez pasture in a northeasterly direction to where it intersects the west fence of the G. Madrigal Ranch, approximately 4/10 mile; thence, following the meanderings of the west fence of the G. Madrigal Ranch in a southeasterly direction, around the east side of the R. Pena addition to the city of Roma, Texas, to a dirt road, approximately 4/10 mile; thence, following the same dirt road in a southerly direction to where it intersects U.S. Highway 83 at the Roma Graveyard, approximately 3/10 mile; thence, following U.S. Highway 83 in an easterly direction to the southwest corner of the Lupe Villarreal pasture on the north side of U.S. Highway 83, approximately 11¼ miles; thence, following the west fence of the Lupe Villarreal pasture in a northerly direction to the northwest corner of the same, approximately ½ mile; thence, following the north fence of the Lupe Villarreal pasture in an easterly direction to the northwest corner of the Roberto Corona pasture, approximately 100 yards; thence, following the north fence of the Roberto Corona pasture in an easterly direction to a corner, approximately 4/10 mile; thence, following the same fence in a northerly direction to where it intersects the West City Limits Road, approximately 4/10 mile; thence, following the West City Limits Road in a northerly direction to the north fence of the Rene Smith property, approximately 3/10 mile; thence, following the east and north fences of the Rene Smith property to where it joins the east fence of the Laguna Ranch, approximately ½ mile; thence, following the east fence of the Laguna Ranch in a northerly direction to a cattle guard on the El Sauz Road, approximately 2 miles; thence, crossing to the El Sauz Road to the east fence of the same and following the El Sauz Road in a southeasterly direction to the northwest corner of the M. Fuentes pasture, approximately 1 4/10 miles; thence, following the north fence of the M Fuentes pasture in an easterly direction to the west fence of the Rene Soliz pasture, approximately 3/10 mile; thence, following the west fence of the Rene Soliz pasture in a southerly direction to the southwest corner of the same, approximately 3/10 mile; thence, following the south fence of the Rene Soliz pasture in an easterly direction to a corner, approximately 1/10 mile; thence, following the same fence in a northerly direction to a corner, approximately 2/10 mile; thence, following the same fence in an easterly direction to a corner, approximately 3/10 mile; thence, following the same fence in a northerly direction to where it joins the North City Limits Road, approximately 4/10 mile; thence, following the meanderings of the North City Limits Road in an easterly direction to where it joins FM Road 755, approximately 7/10 mile; thence, following FM Road 755 in a northeasterly direction to the Los Olmos Creek Bridge, approximately 3/10 mile; thence, crossing under the Los Olmos Creek Bridge in a southerly direction to the east city limits of Rio Grande City, Texas, approximately 80 yards; thence, following the meanderings of the fence along the east city limits of Rio Grande City, Texas, in a southerly direction to the north fence of the Rio

Grande City air strip, approximately ¾ mile; thence, following the north fence of the Rio Grande City air strip in a southeasterly direction to the northeast corner of the same, approximately ⁹⁄₁₀ mile; thence, following the east fence of the Rio Grande City air strip in a southerly direction to the M.P. Railroad right-of-way, approximately ⁵⁄₁₆ mile; thence, crossing the M.P. Railroad right-of-way in a southerly direction to U.S. Highway 83, approximately 100 yards; thence, following U.S. Highway 83 in a southeasterly direction to the Starr-Hidalgo County Line, approximately 16 miles.

(g) That portion of *Hidalgo County* lying generally south of a line beginning at the point where U.S. Highway 83 intersects the Starr-Hidalgo County Line and following the south side of U.S. Highway 83 right-of-way in an easterly direction to the east fence of the Sam Fordyce Ranch, approximately 4 miles; thence, following the east fence of the Sam Fordyce Ranch in a southerly direction to the north fence of the railroad right-of-way, approximately ½ mile; thence, following the north fence of the railroad right-of-way in an easterly direction to where it intersects the Havanna Road, approximately ⁹⁄₁₀ mile; thence, following the Havanna Road in a southerly direction to where it intersects the Old Military Road, approximately 75 yards; thence, following the Old Military Road in an easterly direction to where it intersects the IBWC Levee, approximately 4 miles; thence, following the IBWC Levee in a southeasterly direction to where it intersects the Old Military Road, approximately 8½ miles; thence, following the Old Military Road in an easterly direction to where it joins FM Road No. 1016 at Madero, approximately 1¾ miles; thence, following FM Road No. 1016 in a southeasterly direction to where it joins the Old Military Road, approximately 1 mile; thence, following the Old Military Road in a southeasterly direction to the North Granjeno Road, approximately 1¾ miles; thence, following the North Granjeno Road in an easterly direction to where it intersects Shary Road, approximately ⅝ mile; thence, south on Shary Road to where it intersects the IBWC Levee, approximately 50 yards; thence, following the meanderings of the IBWC Levee in an easterly direction to where it intersects FM Road 1926, approximately 3 miles; thence, following FM Road 1926 in a southerly direction to where it intersects U.S. Highway 281 Spur, approximately 27 miles; thence, following U.S. Highway 281 Spur in an easterly direction to where it becomes U.S. Highway 281, approximately 4⁹⁄₁₀ miles; thence, following U.S. Highway 281 in an easterly direction to where it intersects the Hidalgo-Cameron County Line, approximately 22 miles.

(h) That portion of *Cameron County* lying generally south of a line beginning at the point where the Hidalgo-Cameron County Line intersects U.S. Highway 281 following U.S. Highway 281 in an easterly direction to where it intersects the Willacy County Canal, approximately 200 yards; thence, following the Willacy County Canal in a northerly direction to the C.P.&L. Company double pole power line, approximately ½ mile; thence, following the C.P.&L. Company double pole power line in an easterly direction to where it intersects FM Road No. 1479, approximately 7⅛ miles; thence, south on FM Road No. 1479 to where it intersects a county road, approximately 50 yards; thence, following said county road in a southeasterly direction to where it intersects Ohio Station Road, approximately 1½ miles; thence, southwest on Ohio Station Road to where it intersects the Cameron County Water District drain ditch, approximately ¾ mile; thence, following the Cameron County Water District drain ditch around the San Benito Water District Reservoir in a northeasterly direction to the northeast corner of the San Benito Water District Reservoir, approximately 2½ miles; thence, continuing along the Cameron County Water District drain ditch in a northeasterly direction to where it joins the Resaca Rancho Viejo, approximately 5¼ miles; thence; south and east along the meanderings of the Cameron County Water District drain ditch to where it again joins the Resaca Rancho Viejo, approximately 3⁹⁄₁₀ miles; thence, following the meanderings of the Resaca Rancho Viejo in an easterly direction to where it intersects FM Road 1421, approximately 2 miles; thence, following FM Road 1421 in a southerly direction to where it intersects FM Road 1732, approximately ¾ mile; thence, following FM Road 1732 in an easterly direction to where it intersects Carmen Avenue, approximately 1¾ miles; thence, following Carmen Avenue in a southerly direction to where it intersects the south loop of the Resaca de la Guerra, approximately 3½ miles; thence, following the meanderings of the Resaca de la Guerra in an easterly direction to where it intersects the MP Railroad, approximately 7 miles; thence, following the MP Railroad in a southerly direction to where it intersects Boca Chica Boulevard, approximately 1½ miles; thence, following Boca Chica Boulevard in an easterly direction to where it becomes Boca Chica Road and continuing in the same direction on Boca Chica Road to where it intersects a drain ditch, approximately 9½ miles; thence, following this drain ditch in a northerly direction to where it intersects the Brownsville Ship Channel, approximately 3 miles; thence, following the Brownsville Ship Channel in a northeasterly direction to where it enters the Gulf of Mexico, a distance of approximately 17½ miles.

[49 FR 49611, Dec. 21, 1984, as amended at 50 FR 21796, May 29, 1985]

§ 72.6 Interstate movement of cattle from quarantined areas not eradicating ticks.

Cattle of any quarantined area where tick eradication is not being conducted,[3] which, with an interval of 7 to 12 days between dippings immediately preceding shipment, have been properly dipped twice with a permitted dip as provided in § 72.13, at a designated dipping station approved under § 72.16 that is located within the State of origin of the shipment, or which have been otherwise treated under the supervision of a Veterinary Services inspector in a manner approved in specific cases by the Deputy Administrator, Veterinary Services at such designated dipping station, and which just prior to final dipping are inspected by a Veterinary Services inspector and found to be apparently free from ticks, may, so far as the regulations in this Part are concerned, upon certification by the inspector, be shipped or transported interstate for any purpose upon compliance with the requirements set forth in §§ 72.9 through 72.15.

[36 FR 20358, Oct. 21, 1971; 38 FR 18011, July 6, 1973, as amended at 50 FR 430, Jan. 4, 1985]

§ 72.7 Interstate movement of cattle from cooperating States.

Cattle in areas where tick eradication is being conducted in cooperation with State authorities,[3] which on inspection by a Veterinary Services inspector are found to be apparently free from ticks, may, after one dipping, with a permitted dip as provided in § 72.13, under the supervision of a Veterinary Services inspector and certification by the inspector, be shipped or transported interstate for dip as provided in § 72.13, under the supervision of a Veterinary Services inspector and certification by the inspector, be shipped or transported interstate for any purpose upon compliance with the requirements set forth in §§ 72.9 through 72.15.

[36 FR 20358, Oct. 21, 1971]

§ 72.8 Interstate movement of cattle from free premises upon inspection and certification by Veterinary Services inspector.

Cattle located in areas where tick eradication is being conducted in cooperation with the State authorities, and which are on premises shown by the official records of tick eradication to be free from ticks, may, upon inspection and certification by a Veterinary Services inspector, be shipped or transported interstate for any purpose without dipping upon compliance with the requirements set forth under §§ 72.9, 72.10, 72.12.

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[3] Information as to the identity of such areas may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

§ 72.9 Interstate movements of cattle; inspection and certification by Veterinary Services inspector required.

All interstate movements of inspected and certified and dipped and certified cattle shall be accompanied to final destination by a certificate of a Veterinary Services inspector (which certificate shall show that the cattle so being moved have been dipped as required by § 72.6 or by § 72.7 and are free of ticks, or have been inspected as required by § 72.8 and are free of ticks); all such certificates shall be handled, delivered, kept, and preserved in accordance with the provisions of § 72.16; and all such cattle shall be handled through noninfectious pens, alleys, and chutes, and when shipped shall be loaded into clean and disinfected cars or trucks, and shall not be unloaded in the quarantined area except at such points reserved for noninfested cattle as may from time to time be authorized by Veterinary Services.

§ 72.10 Inspected or dipped and certified cattle subject to restrictions of State of destination.

All such interstate movements of inspected or dipped and certified cattle are subject to such restrictions, which are not inconsistent with the regulations in this subchapter, as may be imposed at destination by the officials of the State, Territory, or the District of Columbia.

§ 72.11 Quarantined area; cattle considered infested; requirements for placing in noninfectious pens or premises.

Cattle of the quarantined area shall be considered infested and shall not be placed in noninfectious pens or premises until after the final inspection or dipping.

§ 72.12 Cattle; exposure to tick infestation after treatment or inspection prohibited.

The cattle shall not be exposed to tick infestation after treatment and/or inspection.

§ 72.13 Permitted dips and procedures.

(a) *Dipping requirements; facilities; handling.* The dipping of cattle for interstate movement shall be done only with a permitted dip and at places where proper equipment is provided for dipping and for handling the cattle in a manner to prevent exposure to infection after the final dipping. Cattle which are to be dipped shall be given an opportunity to drink sufficient water to quench their thirst prior to dipping, be carefully handled, and not dipped while they are in a heated or exhausted condition. Dipped cattle shall not be loaded for shipment until dry.[4]

(b) *Permitted dips.* The dips at present permitted by the Department in official dipping for interstate movement are:

(1) Approved proprietary brands of a Dioxathion (Delnav®) emulsifiable concentrate used at a concentration of 0.125 to 0.150 percent.[4]

(2) Approved proprietary brands of coumaphos (Co-Ral®), 25 percent wettable powder or flowable form labeled for use as a 0.25 percent dip and used at a concentration of 0.125 to 0.250.[4]

(3) Approved proprietary brands of organophosphorous insecticides (Prolate®) if used in a Prolate-water bath where the concentration level is at least 0.15 percent and if used in accordance with the EPA approved label.

(4) Approved proprietary brands of organophosphorous insecticides (Ciodrin®) if used in a concentration of 0.44 to 0.54 percent and if used in accordance with the EPA approved label.

(c) *Approval of dips.* Proprietary brands of dips are permitted to be used for purposes of this part only when approved by the Deputy Administrator, Veterinary Services. Before a dip will be specifically approved as a permitted dip for the eradication of ticks, the Veterinary Services will require that the product be registered under the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 135 et seq.); that its efficacy and stability have been demonstrated; that trials have been conducted to determine that its concentration can be maintained and that under actual field conditions the dipping of cattle with a solution of definite strength will effectually eradicate ticks without injury to the animals dipped.

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[4] Care is required when treating animals and in maintaining required concentration of chemicals in dipping baths. Detailed information concerning the use of, criteria for, and names of proprietary brands of permitted dips for which specific permission has been granted, and concerning the use of compressed air, vat management techniques, and other pertinent information may be obtained from the U.S. Department of Agriculture, APHIS, Veterinary Services, Hyattsville, Md. 20782.

(d) *Tissue residues; restriction on slaughter.* Tissue residues are created following use of certain dips. Animals treated with such dips should not be slaughtered for food purposes until the expiration of such period as may be required under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.). The length of this period shall be specified on each certificate issued by the inspector who supervises the dipping.

[33 FR 18089, Dec. 5, 1968, as amended at 34 FR 12214, July 24, 1969; 36 FR 19157, Sept. 30, 1971; 36 FR 19972, Oct. 14, 1971; 37 FR 13529, July 11, 1972; 38 FR 19012, July 17, 1973; 40 FR 12768, Mar. 21, 1975; 42 FR 19854, Apr. 15, 1977; 47 FR 11002, Mar. 15, 1982; 49 FR 19799, May 10, 1984; 49 FR 32540, Aug. 15, 1984; 50 FR 430, 431, Jan. 4, 1985]

§ 72.14 [Reserved]

§ 72.15 Owners assume responsibility; must execute agreement prior to dipping or treatment waiving all claims against United States.

When the cattle are to be dipped under Veterinary Services supervision the owner of the cattle, offered for shipment, or his agent duly authorized thereto, shall first execute and deliver to a Veterinary Services inspector an application for inspection and supervised dipping wherein he shall agree to waive all claims against the United States for any loss or damage to said cattle occasioned by or resulting from dipping or other treatment under this part, or resulting from any subsequent treatment prior to their interstate shipment, or resulting from the fact that they are later found to be still tick infested, and also for all subsequent loss or damage to any other cattle in the possession or control of such owner which may come into contact with the cattle so dipped or treated.

§ 72.16 Designated dipping stations to be approved by the Deputy Administrator, Veterinary Services on recommendations of State authorities; facilities.

When deemed advisable and upon recommendation by the proper livestock sanitary authorities, designated dipping stations may be approved by the Deputy Administrator, Veterinary Services as points at which cattle of the quarantined area of the State in which said station is located may be inspected, dipped, and certified for interstate movement. The facilities furnished shall include a proper dipping equipment, noninfectious pens constructed in accordance with § 72.17 and a roofed or covered section of pens of sufficient size to protect all dipped animals from exposure to rain or hot sun. All alleys, chutes, and pens shall be paved or properly floored.

[28 FR 5940, June 13, 1963, as amended at 50 FR 430, Jan. 4, 1985]

§ 72.17 Unloading noninfected cattle for rest, feed, and water only, permitted in authorized pens for such purpose.

(a) *Specifications for construction and maintenance.* Cattle of the free area, and cattle of the quarantined area when properly dipped, inspected, and certified in accordance with this part, which are transported interstate by rail through the quarantined area shall not be unloaded therein for rest, feed, and water unless they are unloaded into the properly equipped, noninfectious pens set apart for such cattle at such points as may from time to time be authorized by Veterinary Services. Such noninfectious pens and the platforms, chutes, and alleys leading thereto shall be constructed and maintained in accordance with the specifications set out in paragraph (a)(1) to (6) of this section.

(1) The outside fences inclosing such pens, and the fences on either side of the alleys, chutes, and platforms leading thereto, shall be tight board fences not less than 6 feet high on the inside.

(2) If such pens, alleys, chutes, and platforms are adjacent to pens, alleys,

chutes, and platforms used by cattle of the quarantined area, there shall be between them a space not less than 10 feet wide, which shall be inaccessible to livestock. This space shall be limited on each side by the 6-foot fence required by paragraph (a)(1) of this section. The remaining space around such yards shall be limited as in paragraph (a)(3) of this section.

(3) If such pens, alleys, chutes, and platforms are isolated from other pens, alleys, chutes, or platforms, there shall be built and maintained outside thereof on all sides to which cattle of the vicinity might otherwise approach a cattle-proof fence not less than 5 feet high and not less than 15 feet from the 6-foot fence required by paragraph (a)(1) of this section.

(4) The only means of egress from such pens shall be by way of the alleys, chutes, and platforms inclosed by 6-foot fences as required by paragraph (a)(1) of this section, to cars for reforwarding; and under no circumstances shall there exist any connection between such pens and other adjacent premises.

(5) Such noninfectious premises shall be so located, or such drainage facilities shall be provided therefor, that water from the surrounding area will not flow on to or through them.

(6) Such pens shall be marked by a conspicuous sign bearing the words "Noninfectious Pens" in letters not less than 10 inches in height.

(b) *Materials for use in noninfectious pens; source, shipment, handling.* The hay, straw, or similar materials required for feed and bedding in such noninfectious pens shall be shipped in noninfectious cars from points outside of the quarantined area so handled that they may not become infectious.

§ 72.18 Movement interstate; specification by the Deputy Administrator, Veterinary Services of treatment required when dipping facilities unavailable.

(a) *Tick-infested cattle.* Cattle of the free area which are tick-infested may be moved interstate for any purpose after they have been treated in the same manner as cattle under § 72.6: *Provided, however,* That when dipping equipment is not available at the place where the cattle are, said treatment shall be given at a place and in the manner specified by the Deputy Administrator, Veterinary Services.

(b) *Tick-exposed cattle.* Cattle of the free area which have been exposed to tick infestation may be moved interstate for any purpose after they have been treated in the same manner as cattle under § 72.7: *Provided, however,* That when dipping equipment is not available at the place where the cattle are, said treatment shall be given at a place and in the manner specified by the Deputy Administrator, Veterinary Services.

(c) *Cattle moved contrary to regulations.* Cattle which have been moved from the quarantined area to the free area without first having been treated in the manner provided in either § 72.6 or § 72.7 or inspected in the manner provided in § 72.8 shall not be shipped or moved interstate until they have been treated in the same manner as cattle under § 72.6: *Provided, however,* That when dipping equipment is not available at the place where the cattle are, said treatment shall be given at a place and in the manner specified by the Deputy Administrator, Veterinary Service.

[28 FR 5940, June 13, 1963, as amended at 50 FR 430, Jan. 4, 1985]

§ 72.19 Interstate shipments and use of pine straw, grass, litter from quarantined area; prohibited until disinfected.

Pine straw, grass, or similar litter collected from tick-infested pastures, ranges, or premises may disseminate the contagion of splenetic, southern, or Texas fever; therefore pine straw, grass, or similar litter originating in the quarantined area shall not be transported or moved interstate therefrom or used as packing material or car bedding for commodities or livestock to be transported or moved from the quarantined area of any State, Territory, or the District of Columbia, to or through the free area of any other State, Territory, or the District of Columbia, unless such material is first disinfected in accordance with the provisions of § 72.24.

§ 72.20 Exhibition of noninfected cattle in the quarantined area; restrictions under which permitted.

The exhibition of noninfected cattle at fairs or exhibitions in the quarantined area and their reshipment to the free area without dipping may, by written order of the Deputy Administrator, Veterinary Services, be permitted: *Provided*, That the cattle shall be handled under such conditions as may be prescribed in each case to preclude any danger of the spread of infection.

§ 72.21 Animals infested with or exposed to ticks subject to same restrictions as cattle.

Animals other than cattle which are infested with ticks [Boophilus annulatus (Margaropus annulatus), Boophilus microplus, or Rhipicephalus evertsi evertsi] or exposed to tick infestation shall not be moved interstate unless they are treated, handled, and moved in accordance with the requirements specified in §§ 72.9 through 72.15 and § 72.18 of this part governing the interstate movement of cattle.

§ 72.22 Cars, vehicles, and premises; cleaning and treatment after containing infested or exposed animals.

Cars and other vehicles, and yards, pens, chutes, or other premises or facilities, which have contained interstate shipments of animals infested with or exposed to ticks, shall be cleaned and treated within 72 hours of use and prior to further use in the required concentration with a permitted dip listed in § 72.13 under supervision of a State or Federal inspector or an accredited veterinarian.

[38 FR 21996, Aug. 15, 1973]

§ 72.23 Cars or other vehicles having carried infested or exposed cattle in quarantined area shall be cleaned and treated.

Cars or others vehicles which have carried cattle exposed to or infested with ticks within the quarantined area of any State shall be cleaned and treated in the required concentration with a permitted dip listed in § 72.13 before being moved interstate under supervision of a State or Federal inspector or an accredited veterinarian.

[38 FR 21996, Aug. 15, 1973]

§ 72.24 Litter and manure from carriers and premises of tick-infested animals; destruction or treating required.

The litter and manure removed from cars, boats, or other vehicles and from pens, chutes, alleys, or other premises or inclosures which have contained interstate shipments of tick-infested animals, shall be destroyed or treated by the transportation or yard company, or other owner thereof, under Veterinary Services supervision, by saturating it in the required concentration with a permitted dip listed in § 72.13, or shall be otherwise disposed of under prior permission received from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

[38 FR 21996, Aug. 15, 1973]

§ 72.25 Dipping methods.

Dipping is accomplished by thoroughly wetting the entire skin by either immersion in a chemical solution in a dip vat, or by spraying with a chemical solution using a spray-dip machine or a hand-held sprayer.

[50 FR 430, Jan. 4, 1985]

PART 73—SCABIES IN CATTLE

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73.3 Shipment for purposes other than slaughter; conditions under which permitted.
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73.5 Interstate shipment of undiseased cattle from quarantined area; when permitted.
73.6 Placarding means of conveyance and marking billing of shipments of treated scabby cattle or cattle exposed to scabies.
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Sec.
73.8 Cattle infected or exposed during transit.
73.9 Owners assume responsibility; must execute agreement prior to dipping or treatment waiving all claims against United States.
73.10 Permitted dips; substances allowed.
73.11 Treatment of means of conveyance and premises having contained scabby cattle.
73.12 Ivermectin.

AUTHORITY: Secs. 4–7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791–792, as amended; secs. 1–4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132; 21 U.S.C. 111–113, 115, 117, 120, 121, 123–126, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 28 FR 5945, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

§ 73.1 Interstate movement prohibited.

(a) *Cattle affected with scabies.* No cattle affected with scabies shall be shipped, trailed, driven, or otherwise moved interstate for any purpose except as provided in this part.

(b) *Cattle affected with or exposed to scabies.* No cattle which, just prior to movement, were affected with or exposed to scabies shall be shipped, trailed, driven, or otherwise moved interstate for any purpose except as provided in this part.

(c) *Cattle from area quarantined for scabies.* No cattle shall be shipped, trailed, driven, or otherwise moved interstate from the area quarantined for the disease of scabies in cattle except as provided in this part.

[28 FR 5945, June 13, 1963, as amended at 41 FR 5384, Feb. 6, 1976]

§ 73.1a Notice of quarantine.

[38 FR 32915, Nov. 29, 1973]

EDITORIAL NOTE: For Federal Register citations affecting § 73.1a, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 73.1b Quarantine policy.

The Act of March 3, 1905, as amended (21 U.S.C. 123), authorizes the Secretary of Agriculture to quarantine any State, or any portion of any State, when he determines the fact that any animals in such jurisdiction are affected with any contagious, infectious, or communicable disease of livestock or that the contagion of any such disease exists, or that vectors which may disseminate any such disease exist in such jurisdiction. Pursuant to this authority, the Department has quarantined various areas because of cattle scabies and has issued the regulations in this part governing the interstate movement of cattle from such areas. It is the policy of the Department to quarantine those portions of any State that are clearly identifiable, and in which exist animals affected with cattle scabies, or mites which are the contagion of said disease and not to quarantine an entire State for cattle scabies if the State adopts and enforces requirements for the intrastate movement of cattle that are at least as stringent as the requirements in the regulations in this part for interstate movements of cattle. Further, it is the policy of the Department to remove the quarantine from any quarantined area when it is determined that scabies-affected animals and the mites which are the contagion of scabies no longer exist in such areas.

[38 FR 31671, Nov. 16, 1973]

§ 73.1c Definitions.

For purposes of this Part the following terms shall have the meaning set forth in this section.

(a) *Veterinary Services Inspector.* A veterinarian or livestock inspector employed by Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, in animal health activities, who is authorized to perform the function involved.

(b) *State Inspector.* A veterinarian or livestock inspector regularly employed in animal health activities by a State or a political subdivision thereof, authorized by such State or political subdivision to perform the function involved under a cooperative agreement with the U.S. Department of Agriculture.

[41 FR 5384, Feb. 6, 1976]

§ 73.2 Interstate shipment for immediate slaughter from quarantined or nonquarantined areas; conditions under which permitted.

(a) *Conditions under which permitted after one dipping.* Cattle which, just prior to shipment, were affected with scabies but have been dipped once in a permitted dip (other than a toxaphene dip), under the supervision of a Veterinary Services inspector or State inspector, within 10 days prior to the date of shipment may be shipped or transported interstate for immediate slaughter to a recognized slaughtering center, upon compliance with the following conditions:

(1) They shall not be diverted en route.

(2) The means of conveyance shall be placarded and the billing shall be marked "Treated Scabby Cattle," in accordance with § 73.6.

(b) *After one dipping; to be slaughtered within 14 days or redipped by owner.* Cattle shipped interstate subject to the provisions of paragraph (a) of this section shall be slaughtered within 14 days from the date of the dipping or shall be again dipped by the owner.

(c) *When part of diseased herd not visibly affected.* Cattle of the free area not visibly diseased with scabies, but which may be part of a diseased herd, may be shipped or transported interstate for immediate slaughter to any recognized slaughtering center where separate pens are provided for yarding exposed cattle: *Provided,* That means of conveyance in which the cattle are transported shall be placarded and the billing accompanying the shipment shall be marked "Cattle Exposed to Scabies" in accordance with § 73.6.

(d) *Undiseased herds in quarantined area; conditions under which permitted.* Cattle of herds of the quarantined area which are not diseased with scabies may be shipped, transported, or otherwise moved interstate for immediate slaughter, upon inspection by a Veterinary Services or State inspector within 10 days prior to the date of shipment and when accompanied by a certificate from such inspector showing the cattle to be free from disease.

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791, 792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132, 76 Stat. 663; 7 U.S.C. 450 and 21 U.S.C. 111-113, 115, 117, 120, 121, 123-126, 134b and 134f; 7 CFR 2.17, 2.51, 371.2(d))

[31 FR 8907, June 28, 1966, as amended at 36 FR 23996, Dec. 17, 1971; 38 FR 18011, July 6, 1973; 41 FR 5384, Feb. 6, 1976; 49 FR 10530, Mar. 20, 1984; 49 FR 33120, Aug. 21, 1984]

§ 73.3 Shipment for purposes other than slaughter; conditions under which permitted.

Cattle affected with scabies may be shipped interstate for any purpose if dipped twice in a permitted dip, 10 to 14 days apart, under the supervision of a Veterinary Services inspector or State inspector, and so certified by such inspector, or such cattle may be so shipped if dipped once in a permitted dip under Veterinary Services supervision or State supervision at the point of origin, provided arrangements have been made for the second dipping, under Veterinary Services supervision, en route or at destination within 10 to 14 days after the first dipping. If shipped in the latter manner the means of conveyance containing the cattle shall be placarded and the billing shall be marked "Treated Scabby Cattle," in accordance with § 73.6.

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791, 792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132, 76 Stat. 663; 7 U.S.C. 450 and 21 U.S.C. 111-113, 115, 117, 120, 121, 123-126, 134b and 134f; 7 CFR 2.17, 2.51, 371.2(d))

[28 FR 5945, June 13, 1963, as amended at 41 FR 5384, Feb. 6, 1976; 49 FR 10530, Mar. 20, 1984; 49 FR 33120, Aug. 21, 1984]

§ 73.4 Interstate shipment of exposed but not visibly diseased cattle from a quarantined or nonquarantined area; conditions under which permitted.

Cattle not visibly diseased with scabies, but which are known to be part of a diseased herd or to have come in contact with diseased cattle or infectious means of conveyance or premises, may be shipped interstate for any purpose if dipped at the point of origin, under the supervision of a Veterinary Services inspector or State inspector, in a permitted dip, or the cattle may be dipped en route by special permission first had and obtained from the Deputy Administrator, Veterinary Services; but in such event the means of conveyance shall be placarded and the billing shall be marked "Cattle Exposed to Scabies," in accordance with § 73.6, and the cattle shall not be permitted to mingle with other cattle until disposed of in accordance with the regulations in this part.

[28 FR 5945, June 13, 1963, as amended at 41 FR 5384, Feb. 6, 1976]

§ 73.5 Interstate shipment of undiseased cattle from quarantined area; when permitted.

Cattle of any herd in any quarantined area, which herd is not diseased with scabies, may be shipped, transported, or otherwise moved interstate for any purpose upon inspection by a Veterinary Services or State inspector within 10 days prior to the date of shipment and when accompanied by a certificate from such inspector showing the cattle to be free from such disease or exposure thereto. When it is determined by the Deputy Administrator, Veterinary Services that all cattle of all herds in any quarantined area have been inspected for scabies by a Veterinary Services or State inspector, that all the infected or exposed herds have been identified, and that all the infected herds have been dipped twice, and all the exposed herds have been dipped in a permitted dip as prescribed in § 73.10, under supervision of a Veterinary Services or Veterinary Services-approved inspector, cattle of herds in such area which are not diseased with or exposed to scabies may be moved interstate in accordance with this section, without further Veterinary Services inspection or certification, directly to a slaughtering plant where Federal Meat Inspection is maintained: *Provided further,* that treatment with ivermectin may be used in lieu of dipping for a herd of cattle treated together if the herd is physically separated for 14 days following treatment from all cattle not a part of the herd treated together with ivermectin. Information may be obtained from a Veterinary Services inspector whether a determination as required by this section is currently applicable to authorize such movement. Cattle moved interstate under this section shall not be diverted en route and must be accompanied by a waybill or similar document, or a statement signed by the owner or shipper of the cattle, stating: (a) That the cattle are not known to be infected with scabies or exposed thereto; (b) [Reserved]; (c) the purpose for which the cattle are to be moved; (d) the number of the cattle; (e) the point from which the cattle are to be moved interstate; (f) that the cattle shall not be diverted en route; and (g) the name and address of the owner or shipper of the cattle.

(Approved by the Office of Management and Budget under control number 0579-0051)

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791, 792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132, 76 Stat. 663; 7 U.S.C. 450 and 21 U.S.C. 111-113, 115, 117, 120, 121, 123-126, 134b and 134f; 7 CFR 2.17, 2.51, 371.2(d))

[31 FR 8907, June 28, 1966 as amended at 36 FR 23996, Dec. 17, 1971; 38 FR 10252, Apr. 26, 1973; 38 FR 18011, July 6, 1973; 41 FR 5384, Feb. 6, 1976; 48 FR 57472, Dec. 30, 1983; 49 FR 10530, Mar. 20, 1984; 49 FR 33120, Aug. 21, 1984]

§ 73.6 Placarding means of conveyance and marking billing of shipments of treated scabby cattle or cattle exposed to scabies.

When cattle are shipped as "Treated Scabby Cattle," or "Cattle Exposed to Scabies," the transportation companies shall securely affix to and maintain upon both sides of each means of conveyance carrying such cattle a durable, conspicuous placard, not less than 5½ by 8 inches in size, on which shall be printed with permanent black ink in boldfaced letters, not less than 1½ inches in height, the words, "Treated Scabby Cattle," or "Cattle Exposed to Scabies," as the case may be. These placards shall also show the name of the place from which the shipment was made, the date of the shipment (which must correspond to the date of the waybills and other papers), the name of the transportation company, and the name of the place of destination. The carrier issuing the waybills, conductors' manifests, memoranda, and bills of lading pertaining to such shipments shall plainly write or stamp upon the face of each such paper the words, "Treated Scabby Cattle," or "Cattle Exposed to Scabies," as the case may be. If for any reason the placards required by this part have not been affixed to the means of conveyance as aforesaid, or the placards have been removed, destroyed, or rendered illegible, or the cattle are rebilled or are transferred to other means of conveyance, the placards shall be immediately affixed or replaced by the carrier, and the new waybills shall be marked as aforesaid by the carrier issuing them, the intention being that the billing accompanying the shipment shall be marked and the means of conveyance containing the cattle shall be placarded "Treated Scabby Cattle," or "Cattle Exposed to Scabies," as the case may be, from the time of shipment until the cattle arrive at destination or point of dipping and the disposition of the means of conveyance is indicated by a Veterinary Services inspector or State inspector.

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791, 792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132, 76 Stat. 663; 7 U.S.C. 450 and 21 U.S.C. 111-113, 115, 117, 120, 121, 123-126, 134b and 134f; 7 CFR 2.17, 2.51, 371.2(d))

[28 FR 5945, June 13, 1963, as amended at 41 FR 5384, Feb. 6, 1976; 49 FR 10530, Mar. 20, 1984; 49 FR 33120, Aug. 21, 1984]

§ 73.7 Movement from quarantined to free area and shipment therefrom; restrictions under which permitted.

No person, firm, or corporation shall deliver for transportation, transport, drive on foot, or otherwise move interstate from the free area of any State, Territory, or the District of Columbia any cattle which have been moved from the quarantined area of the same State, Territory, or the District of Columbia into such free area: *Provided, however,* That such cattle may be delivered for transportation, transported, driven on foot, or otherwise moved interstate for the purposes for which the shipment, transportation, or other movement interstate of cattle of the quarantined area is permitted by this part, *Provided,* That in such shipment and transportation or other movement the requirements of this part governing the shipment and transportation or other movement of cattle of the quarantined area are strictly complied with: *And provided further,* That this section shall not apply to cattle of the quarantined area which, before being moved into the free area, are certified by a Veterinary Services inspector or State inspector as free from disease and are accompanied by such certificate in their shipment by transportation or other movement interstate.

(Approved by the Office of Management and Budget under control number 0579-0051)

(44 U.S.C. 3506)

[28 FR 5945, June 13, 1963, as amended at 41 FR 5384, Feb. 6, 1976; 48 FR 57472, Dec. 30, 1983]

§ 73.8 Cattle infected or exposed during transit.

(a) *Healthy cattle from unquarantined State exposed en route.* Should healthy cattle in transit from a State not quarantined by the Secretary of Agriculture for scabies in cattle be unloaded en route and placed in infectious premises, they shall be treated as exposed cattle, and their further movement shall be subject to the provisions of this part with respect to the movement of exposed cattle.

(b) *Interstate shipments of cattle under Veterinary Services or State certificate found affected or exposed en route.* Cattle shipped interstate under a certificate from a Veterinary Services inspector or State inspector or other cattle which are found en route to be affected with scabies or to have been exposed thereto, shall thereafter be handled in the same manner as diseased or exposed cattle are required by this part to be handled, and the means of conveyance and the chutes, alleys, and pens which have been occupied by diseased animals shall be cleaned and disinfected as provided in §§ 71.4 through 71.11 of this subchapter.

[28 FR 5945, June 13, 1963, as amended at 41 FR 5384, Feb. 6, 1976]

§ 73.9 Owners assume responsibility; must execute agreement prior to dipping or treatment waiving all claims against United States.

When the cattle are to be dipped under Veterinary Services supervision or control, the owner of the cattle offered for shipment, or his agent duly authorized thereto, shall first execute and deliver to a Veterinary Services inspector an application for inspection and supervised dipping wherein he shall agree to waive all claims against the United States for any loss or damage to said cattle occasioned by or resulting from dipping or other treatment under this part, or resulting from any subsequent treatment prior to their interstate shipment, or resulting from the fact that they are later found to be still scabies infested, and also for all subsequent loss or damage to any other cattle in the possession or control of such owner which may come into contact with the cattle so dipped or treated.

[41 FR 4012, Jan. 28, 1976]

§ 73.10 Permitted dips; substances allowed.

(a) The dips at present permitted by the Department for the treatment, as required in this part, of cattle affected with or exposed to scabies, are as follows:

(1) Lime-sulphur dip, other than proprietary brands thereof, made in the proportion of 12 pounds of unslaked lime (or 16 pounds of commercial hydrated lime, not airslaked lime) and 24 pounds of flowers of sulphur or sulphur flour to 100 gallons of water; or a specifically permitted proprietary brand of lime-sulphur dip.

(2) Dips made from specifically permitted proprietary brand emulsions of toxaphene and maintained throughout the dipping operation at a concentration between 0.50 and 0.60 percent toxaphene. Animals treated by such dips should not be slaughtered for food purposes until the expiration of such period as may be required under the Federal Meat Inspection Act (21 U.S.C., Supp. III, 601 et seq.). The length of this required period shall be specified on each certificate issued by the Veterinary Services inspector or State inspector who supervises the dipping with such dips.

(3) Approved proprietary brands of coumaphos (Co-Ral®), 25 percent wettable powder or flowable form used at a concentration of 0.30 percent.

(4) Approved proprietary brands of organophosphorous insecticides (Prolate®)used at a concentration of 0.15 percent to 0.25 percent.

(b) The dipping bath for lime-sulphur dip must be used at a temperature of 95° to 105° F., and must be maintained through the dipping operation at a concentration of not less than 2 percent of "sulphide sulphur", as indicated by the field test for lime-sulphur dipping baths approved by the Veterinary Services.[1] The dipping bath for toxaphene emulsions must be kept within a temperature range of 40°-80° F., and at a concentration between 0.50 and 0.60 percent throughout the dipping operations.[2]

(c) Proprietary brands of lime-sulphur or toxaphene dips may be used in official dipping only after specific permission therefor has been granted by the Deputy Administrator, Veterinary Services.[3] Before a dip will be specifically approved as a permitted dip for the eradication of scabies in cattle, the Veterinary Services will require that the product be registered under the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 135 et seq.); that is efficacy and stability have been demonstrated; that trials have been conducted to determine that its concentration can be maintained and that under actual filed conditions the dipping of cattle in a bath of definite strength will effectually eradicate scabies infection without injury to the animals dipped.

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[1] The field test for lime-sulphur dipping baths is described in U.S. Department of Agriculture Bulletin 163, for sale by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402, at 5 cents a copy.

[2] Care must be exercised in dipping animals and in maintaining the bath at the standard concentration. Detailed instructions will be issued for the guidance of employees who may be called upon to use them in the scabies eradication program.

[3] Information as to the names of such dips may be obtained from the Veterinary Services or a Veterinary Services inspector.

[34 FR 7443, May 8, 1969; as amended at 39 FR 39715, Nov. 11, 1974; 40 FR 12768, Mar. 21, 1975; 40 FR 42179, Sept. 11, 1975; 41 FR 5384, Feb. 6, 1976; 41 FR 37307, Sept. 3, 1976; 50 FR 431, Jan. 4, 1985]

§ 73.11 Treatment of means of conveyance and premises having contained scabby cattle.

Means of conveyance, yards, pens, sheds, chutes, or other premises or facilities which have contained cattle of a consignment in which scabies is found shall be treated within 72 hours of use and prior to further use in the required concentration with a permitted dip listed in § 73.10 under supervision of a State or Federal inspector or an accredited veterinarian.

[38 FR 21996, Aug. 15, 1973, as amended at 41 FR 5384, Feb. 6, 1976]

§ 73.12 Ivermectin.[1]

(a) Cattle affected with scabies or which just prior to movement were affected with or exposed to scabies may be moved interstate from a nonquarantined area after being treated with ivermectin under the supervision of a Veterinary Services inspector or State inspector in accordance with the directions on the label of the drug if the following conditions are met:

(1) Such cattle are kept physically separated for 14 days following treatment from all cattle not part of the group treated together with ivermectin (regardless of whether the cattle are moved interstate before the end of the 14-day period); and

(2) If such cattle are moved interstate before the end of the 14th day following treatment, at the time of interstate movement they are accompanied by a certificate issued and signed by a Veterinary Services inspector or State inspector identifying the group of cattle treated with ivermectin and stating the date on which the cattle were treated with ivermectin; and

(3) If such cattle are moved interstate before the end of the 14th day following treatment, at the time of interstate movement the means of conveyance carrying them is placarded and the billing marked in accordance with § 73.6.

NOTE: Cattle from nonquarantined areas which are not affected with scabies or which just prior to movement were not affected with or exposed to scabies may be moved interstate without restrictions under this Part. Accordingly, cattle from nonquarantined areas which had been treated with ivermectin more than 14 days before movement interstate may be moved interstate without restriction under this Part unless following treatment they become affected with scabies or just prior to movement become affected with or exposed to scabies.

(b) Cattle may be moved interstate from a quarantined area after being treated with ivermectin under the supervision of a Veterinary Services inspector or State inspector in accordance with the directions on the label of the drug if the following conditions are met:

(1) Such cattle are moved interstate within 21 days following treatment with ivermectin; and

(2) Such cattle are kept physically separated for 14 days following treatment from all cattle not part of the group treated together with ivermectin (regardless of whether the cattle are moved interstate before the end of the 14 day period); and, if such cattle are moved within the 15- to 21-day period following treatment, they remain kept physically separated from all cattle not a part of the group treated together with ivermectin until after they are moved interstate; and

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[1] Tissue residues remain following treatment with ivermectin. Cattle treated with ivermectin are not allowed to be slaughtered for food purposes until the expiration of such period as may be required under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*). Further, the animal drug regulations in 21 CFR Parts 522 and 556 promulgated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) contain limitations on the use of ivermectin and contain tolerances for ivermectin in edible cattle tissue. With respect to the limitations 21 CFR Part 522 provides the following: "For subcutaneous use only. Not for intramuscular use. Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Federal law restricts this drug to use by or on the order of a licensed veterinarian."

(3) Such cattle are accompanied at the time of interstate movement by a certificate issued and signed by a Veterinary Services inspector or State inspector identifying the group of cattle treated with ivermectin and stating the date on which the cattle were treated with ivermectin; and

(4) If such cattle are moved interstate before the end of the 14 day period following treatment, at the time of interstate movement the means of conveyance carrying them is placarded and the billing marked in accordance with § 73.6.

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791, 792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132, 76 Stat. 663; 7 U.S.C. 450 and 21 U.S.C. 111-113, 115, 117, 120, 121, 123-126, 134b and 134f; 7 CFR 2.17, 2.51, 371.2(d))

[49 FR 10530, Mar. 20, 1984 and 49 FR 33120, Aug. 21, 1984]

PART 74—[RESERVED]

PART 75—COMMUNICABLE DISEASES IN HORSES, ASSES, PONIES, MULES, AND ZEBRAS

DOURINE IN HORSES AND ASSES

Sec.

75.1 Movement of animals from quarantined areas; Veterinary Services inspection and certification required.
75.2 Breeding animals in quarantined areas; interstate movement within 18 months prohibited except on Veterinary Services certification as having passed complement-fixation test.
75.3 Appraisal of and compensation for animals.

EQUINE INFECTIOUS ANEMIA (SWAMP FEVER)

75.4 Notice relating to existence of equine infectious anemia (swamp fever), official test and conditions of interstate movement of reactors.

CONTAGIOUS EQUINE METRITIS (CEM)

75.5 Definitions.
75.6 General restrictions.
75.7 Areas quarantined.
75.8 Restrictions on interstate movement from or through Kentucky.
75.9 Restrictions on interstate movement from or through Missouri.
75.10 Procedures for breeding mares to be released from Federal quarantine because of CEM.

AUTHORITY: 21 U.S.C. 111-113, 115, 117, 120, 121, 123-126, 134-134h; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 28 FR 5950, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

DOURINE IN HORSES AND ASSES

§ 75.1 Movement of animals from quarantined areas; Veterinary Services inspection and certification required.

No horses or asses shall be offered for interstate shipment, shipped, transported, driven, or trailed or otherwise moved interstate from an area quarantined by the Secretary of Agriculture for dourine, without Veterinary Services inspection and certification of freedom from the disease for the purpose of the particular movement. Owners and custodians of horses or asses for whom inspection is made shall provide such reasonable facilities and render such assistance as may be required by the inspector.

§ 75.2 Breeding animals in quarantined areas; interstate movement within 18 months prohibited except on Veterinary Services certification as having passed complement-fixation test.

If stallions or jacks shall be allowed to run at large in an area quarantined by the Secretary of Agriculture for dourine, or if there shall be any breeding of horses or asses in a herd in the quarantined area in which there is a horse or an ass which has been exposed to the infection of dourine, within 18 months after the said exposure, the interstate movement of any horses or asses from the said area is absolutely prohibited unless and until such horses and asses have been certified by a Veterinary Services inspector as having passed the complement-fixation test for such disease.

§ 75.3 Appraisal of and compensation for animals.

Animals to be destroyed because of dourine will be appraised and paid for in accordance with the provisions of the indemnity regulations as set forth in Part 52, Subchapter B of this title.

[30 FR 5790, Apr. 24, 1965]

EQUINE INFECTIOUS ANEMIA (SWAMP FEVER)

§ 75.4 Notice relating to existence of equine infectious anemia (swamp fever), official test and conditions of interstate movement of reactors.

(a) Notice is hereby given that equine infectious anemia (swamp fever), a communicable disease of horses, asses, mules, ponies, and zebras exists in all States.

(b) *Definitions.* For the purposes of this section, the following terms shall have the meanings set forth in this paragraph. See also definitions in § 71.1 of this chapter.

(1) *Official test.* The Agar gel immuno/diffusion test for equine infectious anemia conducted in a laboratory approved by the Deputy Administrator, Veterinary Services, for the purpose of conducting this test. Laboratories will be approved by the Deputy Administrator following the determination by him that the laboratory: (i) Has adequately trained technical personnel assigned to conduct the test, (ii) uses USDA licensed antigen, (iii) follows standard test protocol, (iv) meets check test proficiency requirements, and (v) reports all test results to State and Federal animal health officials.[1]

(2) *Reactor.* Any horse, ass, mule, pony, or zebra which discloses a positive reaction to the official test.

(3) *Officially identified.* The permanent identification of a reactor using the National Uniform Tag code number assigned by the Department to the State in which the reactor was tested followed by the letter "A"[2] which markings shall be permanently applied to the animal by a Veterinary Services inspector, State inspector, or accredited veterinarian who shall employ for the purpose a hot iron or chemical brand, freezemarking or a lip tattoo. If hot iron or chemical branding or freezemaking is employed, the markings shall be not less than two inches high and shall be applied to the left shoulder or left side of the neck of the reactor. If a lip tattoo is employed, the tattoo shall be not less than one inch high and three-fourths of an inch wide and shall be applied to the inside surface of the upper lip of the reactor.

(4) *Certificate.* An official document issued by a State or Veterinary Services inspector or by an accredited veterinarian at the point of origin of the interstate shipment on which are listed: (i) The description, including age, breed, color, sex, and distinctive markings when present (such as brands, tattoos, scars, or blemishes) on each reactor to be moved; (ii) the number of animals covered by the document; (iii) the purpose for which the animals are to be moved; (iv) the points of origin and destination; (v) the consignor; and (vi) the consignee; and which states that the animal or animals identified on the certificate meet the requirements of § 75.4(c).

(5) *Veterinary Services inspector.* A veterinarian or livestock inspector employed by Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, in animal health activities, who is authorized to perform the function involved.

(6) *State inspector.* A veterinarian or livestock inspector regularly employed in animal health activities by a State or a poltical subdivision thereof, authorized by such State or political subdivision to perform the function involved under a cooperative agreement with the U.S. Department of Agriculture.

(7) *Accredited veterinarian.* An accredited veterinarian as defined in Part 160 of this chapter.

(c) Any reactor to an official test shall be classified as affected with equine infectious anemia, and shall not be moved interstate unless:

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[1] Information as to the names of laboratories approved for running the official test can be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Center Building, Hyattsville, Maryland 20782.

[2] Information as to the National Uniform Tag code number system can be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Center Building, Hyattsville, Maryland 20782.

(1) It is officially identified, and accompanied by a certificate as defined in § 75.4(b)(4); and

(2) It is moved interstate, for immediate slaughter, to a federally inspected slaughtering establishment operated under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or to a State-inspected slaughtering establishment which has inspection by a State inspector at the time of slaughter, or to a diagnostic or research facility designated by the Deputy Administrator, as provided in § 71.3(e),[3] or

(3) The reactor is disclosed on an official test conducted in a State other than the State in which the home farm of the reactor is located, and such reactor is moved interstate to its home farm under a certificate issued by a State or Veterinary Services inspector or by an accredited veterinarian upon his determination, after consultation with the State officials concerned, that the reactor so moved will be maintained segregated from other equine animals and quarantined under State authority on the premises of its home farm until natural death, slaughter, or disposition by euthanasia.

(d) The Deputy Administrator may deny approval of any laboratory to conduct the official test upon a determination that the laboratory does not meet the criteria for approval under this part and at any time may withdraw approval of any laboratory to conduct the official test upon a determination that any of the requirements for approval under this part are not complied with. In the case of denial, the operator of the laboratory will be informed of the reasons for the action and, upon request, shall be afforded an opportunity for a hearing with respect to the merits or validity of such action in accordance with the rules of practice which shall be adopted for the proceeding. In the case of a withdrawal, before such action is taken, the operator of the laboratory will be informed of the reasons for the proposed action and, upon request, shall be afforded an opportunity for a hearing with respect to the merits or validity of such action in accordance with rules of practice which shall be adopted for the proceeding. However, such withdrawal shall become effective pending final determination in the proceeding when the Deputy Administrator determines that such action is necessary to protect the public health, interest, of safety. Such withdrawal shall be effective upon oral or written notification, whichever is earlier, to the operator of the laboratory. In the event of oral notification, written confirmation shall be given to the operator of the laboratory as promptly as circumstances allow. This withdrawal shall continue in effect pending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Deputy Administrator. In addition to withdrawal of approval when the requirements for approval are not complied with, approval will be automatically withdrawn by the Deputy Administrator when the operator of any approved laboratory notifies the National Veterinary Services Laboratories in Ames, Iowa, in writing, that the laboratory no longer conducts the official test.

[38 FR 20441, Aug. 1, 1973, as amended at 50 FR 30412, July 26, 1985]

CONTAGIOUS EQUINE METRITIS (CEM)

§ 75.5 Definitions.

For purposes of this section, the following terms shall mean:

(a) *Accredited Veterinarian.* An accredited veterinarian as defined in Part 160 of this chapter.

(b) *Affected Animal.* An animal from which bacteria causing CEM has been identified in a State or Federal animal disease diagnostic laboratory by standard bacteriological methods.

(c) *Animal.* Any horse, ass, mule, zebra or other equidae.

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[3] Research facilities will be designated by the Deputy Administrator upon request and after a determination by the Deputy Administrator that the facility is secure and will prevent exposure to other equine animals. Information as to the names and locations of designated research facilities can be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Center Building, Hyattsville, Maryland 20782.

(d) *Certificate.*[3a] An official document issued by a State or Veterinary Services inspector or by an accredited veterinarian at the point of origin of a shipment of animals to be moved under this section which states:

(1) The description of each animal covered by the certificate including the name, breed, color, sex, and distinctive markings, such as brands, tattoos, scars, or blemishes, if any;

(2) The age of each animal covered by the certificate, with the age of each weanling or yearling recorded in days;

(3) The number of animals covered by the certificate;

(4) The purpose for which the animals are to be moved;

(5) The points of origin and destination of the movement;

(6) The names of the consignor and the consignee; and,

(7) Certification by the person issuing the certificate that the animal or animals identified on the certificate are not affected or exposed animals.

(8) On any mare bred since January 1, 1978, the certificate shall further state: (i) The name of stallion to which the mare was bred; (ii) the date or dates of breeding; and (iii) the farm name where the stallion was located.

(e) *CEM.* Contagious Equine Metritis.

(f) *Exposed Animal.* An animal which has had sexual contact with an affected animal, or which has had genital contact with any animal or equipment which has had any gential contact with an affected animal.

(g) *Permit.*[4] A completed VS Form 1-27 issued by a State or Veterinary Services inspector or by an accredited veterinarian for the interstate movement of affected or exposed animals for slaughter which in addition to the information required to be stated on the form shall state a description of each animal to be moved including the name, age, color, and distinctive markings, such as brands, tattoos, scars, or blemishes, if any.

(h) *State Inspector.* A veterinarian or livestock inspector regularly employed in animal health activities by a State or a political subdivision thereof, authorized by such State or political subdivision to perform the function involved under a cooperative agreement with the United States Department of Agriculture.

(i) *Veterinary Services Inspector.* A veterinarian or livestock inspector employed by Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, in animal health activities, who is authorized to perform the function involved.

(j) *Weanling or Yearling.* Any horse not more than 731 days old on the date of interstate movement.

(k) *Known infected premises.* A premises where an affected animal has been bred.

(l) *Breeding animal.* Any mare or stallion more than 731 days old on the date of interstate movement.

(m) *Artificial insemination.* The collection of semen from a stallion through use of an artificial vagina and the introduction of semen collected by that means into the female reproductive organs of a mare without sexual contact.

[43 FR 22926, May 30, 1978, as amended at 43 FR 25993, June 16, 1978; 44 FR 28296, May 15, 1979]

§ 75.6 General restrictions.

(a) Notice is hereby given that CEM, a communicable disease of horses, asses, mules, zebras, and other equidae exists in each area specified in § 75.7 of this part.

(b) Affected or exposed animals shall not be moved interstate except in accordance with the regulations in this part.

[43 FR 22927, May 30, 1978]

§ 75.7 Areas quarantined.

(a) Notice is hereby given that because of the existence of CEM in the breed of Thoroughbred horses in certain areas, and because of the nature and extent of such disease, the following areas are hereby quarantined:

[3a] The person issuing the certificate shall promptly forward copies of each certificate issued to the Chief Animal Health official of the State of origin and the Chief Animal Health official of the State of destination, respectively.

[4] The person issuing each permit shall promptly forward copies of each permit issued to Animal Health officials indicated on the original and each copy of VS Form 1-27.

(1) *Kentucky.*

(i) *Bourbon County.* That portion of the premises of Elmendorf Farm No. 2, located 0.5 mile east of intersection of Bethleham Pike and Iron Works Pike on the north side of Iron Works Pike described as beginning at the northwest corner of barn No. 1, then, north along a double fence approximately 500 feet, then, west along a double fence approximately 200 feet, then south along a double fence approximately 500 feet, then east along a double fence to the point of beginning, containing approximately 4 acres.

(ii) *Boyle County.* That portion of the premises of Happy Valley Farm located on the southwest side of Bluegrass Pike 0.5 mile northwest of the intersection of Kentucky Highway 1915 and Bluegrass Pike, intersection is located 0.9 mile west of U.S. Highway 127, then, proceed from the farm entrance southwest 0.8 mile to a structure known as the concrete barn, then proceed southeast from the southwest corner of the concrete barn approximately 600 feet to the corner post of the paddock, described as beginning at the corner post; then, approximately 400 feet southwest along a double fence line; then, approximately 220 feet southeast along a single fence; then, approximately 400 feet northeast along a single fence; then, approximately 220 feet northwest along a single fence line to the point of beginning, containing approximately 2 acres.

(iii) *Fayette County.* That portion of the premises of the University of Kentucky Experiment Station located on the west side of Newtown Pike 100 yards north of Interstate 75 underpass, then, on entrance road to a barn marked "B" described as beginning at the south corner of the lot of barn "B"; then, north approximately 944 feet along double fence; then, east approximately 1326 feet along a double fence line; then, south approximately 950 feet along a double fence line; then, west approximately 1326 feet along a double fence line to the point of beginning, containing approximately 40 acres including a barn marked "C" which is located on the east end of the enclosed quarantine area.

(iv) *Mercer County.* That portion of the premises of Bellows Mill Farm located on the north side of Bellows Mill Road 2.8 miles east of the intersection of Beaumont Road and Bellows Mill Road then proceed 0.4 mile northwest from the entrance of the farm to the southeast corner of a paddock described as beginning at the entrance to the paddock at the southeast corner; then, north approximately 250 feet along a single fence line; then, west approximately 560 feet along a single fence line; then, south approximately 250 feet along a single fence line; then, east approximately 560 feet along a single fence to the point of beginning, containing approximately 8 acres including a tobacco barn and a stripping building on the north central portion of the paddock.

(v) *Oldham County.* That portion of the premises of Hermitage Farm located 3 miles northeast of Goshen, on the southeast side of U.S. Highway 42, described as beginning at a post on the southeast side of Circle Drive, then in a southeasterly direction along a single fence approximately 1,000 feet, then in a south direction along a double fence approximately 400 feet, then in a northwestern direction along a single fence approximately 400 feet to corner post, then along an irregular single fence line to the point of beginning, containing approximately 3 acres.

(vi) *Scott County.* (A) That portion of the premises of Elkhorn Stud Farm located in the southwest corner of the intersection of Interstate 75 and U.S. Highway 460, then proceed due west from the northwest corner of the concrete barn approximately 150 feet to the northeast corner of the second paddock on the south side of the lane described as beginning at a corner post; then, west approximately 120 feet along the fence line; then, south approximately 160 feet along the fence line; then, east approximately 120 feet along the fence line; then, north approximately 160 feet along the fence line to the point of beginning, containing approximately 0.35 acre.

(B) That portion of the premises of the J. T. Lundy Farm located 0.6 mile north of the intersection of U.S. Highway 421 and Moore's Mill Road on the east side of Moore's Mill Road to the entrance, then cross Elkhorn Creek on the main farm lane for 0.2 mile to the isolation barn, then approximately 100 feet in a northwest direction from the northeast corner of the isolation barn across the lane to the paddock gate to the quarantined area described as beginning at the paddock gate, then along a double fence in a northeast direction approximately 200 feet, then along a double fence in a north direction for approximately 200 feet, then along a double fence in a west direction for approximately 160 feet, then along a double fence in a southwest direction for approximately 400 feet, then along a double fence in a southeast direction for approximately 60 feet, then along a double fence in a northeast direction for approximately 250 feet to the point of beginning, containing approximately 2.5 acres.

(b) Notice is hereby given that because of the existence of CEM in various breeds of horses in certain areas of Missouri and because of the nature and extent of such disease, the following areas are hereby quarantined:

(1) *Missouri.*

(i) [Reserved]

(ii) *Callaway County.* The premises of Carl Block located in sec. 34, T. 48 N., R. 11 W.

(iii) *Ste. Genevieve County.* The premises of Dr. Robert Hoye located in sec. 18, T. 37, R. 8.

[43 FR 22927, May 30, 1978, as amended at 44 FR 28296, May 15, 1979; 44 FR 40880, July 13, 1979; 44 FR 60257, Oct. 19, 1979; 44 FR 75620, Dec. 21, 1979; 45 FR 1002, Jan. 4, 1980; 45 FR 2837, Jan. 15, 1980; 45 FR 8580, Feb. 8, 1980; 45 FR 26316, Apr. 18, 1980; 46 FR 22565, Apr. 20, 1981; 46 FR 37018, July 17, 1981; 48 FR 38794, Aug. 26, 1983]

§ 75.8 Restrictions on interstate movement from or through Kentucky.

(a) Except as provided in paragraph (b) of this section, no horse of the Thoroughbred breed shall be moved interstate from or through any quarantined area specified in § 75.7(a) of this part except in accordance with the following conditions:

(1) A gelding may be moved interstate without restriction;

(2) A weanling or yearling may move interstate if accompanied by a certificate;

(3) A mare or stallion which is not an affected or exposed animal and which has not been bred naturally in the quarantined area after August 30, 1977, may move interstate from the quarantined area for other than breeding purposes if accompanied by a certificate;

(4) A mare or stallion which is not an affected or exposed animal and which has not been bred in the quarantined area except by artificial insemination after August 30, 1977, may move interstate from the quarantined area for breeding purposes if such breeding will be performed only by artificial insemination in the presence of and certified to by a State or Veterinary Services Inspector, and if such horses are accompanied by a certificate;

(5) A mare bred after March 27, 1978, on a known infected premises may move from the quarantined area if it has been determined by a State or Veterinary Services Inspector through epidemiological investigation that she is not an affected or exposed animal and she is accompanied by a certificate;

(6) A mare not bred on a known infected premises may move from the quarantined area if it has been determined by a State or Veterinary Services Inspector through epidemiological investigation that she is not an affected or exposed animal and she is accompanied by a certificate;

(7) A mare or stallion bred on a premises which is not a known infected premises may move from a quarantined area if it has been determined by a State or Veterinary Services Inspector through epidemiological investigation that the animal is not an affected or exposed animal and if the animal is accompanied by a certificate; or

(8) A horse which is not an affected or exposed animal may move interstate through the quarantined area if accompanied by a certificate and if moved through such area without contact with other animals while in such area.

(b) *Movement of animals for immediate slaughter.* (1) No affected or exposed animal shall be moved interstate except for immediate slaughter directly to a federally inspected slaughtering establishment operated under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or to a State-inspected slaughtering establishment which has inspection by a State inspector at the time of slaughter and only if accompanied by a permit.

(2) Animals other than affected or exposed animals may be moved interstate for immediate slaughter only if they comply with all of the provisions for movement of affected or exposed animals for slaughter in subparagraph (b)(1) of this section.

(c) *Cleaning and disinfection.* Any means of conveyance used to transport affected or exposed animals interstate shall be thoroughly cleaned and disinfected after such movement in accordance with the provisions of §§ 71.6, 71.7, 71.10, 71.11, and 71.12 of the regulations in this subchapter.

[43 FR 22927, May 30, 1978, as amended at 43 FR 25993, June 16, 1978; 44 FR 28296, May 15, 1979]

§ 75.9 Restrictions on interstate movement from or through Missouri.

(a) Except as provided in paragraph (b) of this section, no animal shall be moved interstate from or thorough any quarantined area specified in § 75.7(b) of this part except in accordance with the following conditions:

(1) A gelding may be moved interstate without restriction;

(2) A weanling or yearling may be moved interstate if accompanied by a certificate;

(3) A breeding animal which is not an affected or exposed animal may move interstate from a quarantined area for other than breeding purposes if accompanied by a certificate; or

(4) A breeding animal which is not an affected or exposed animal may be moved interstate from a quarantined area for breeding purposes if such breeding will be performed only by artifical insemination in the presence of and certified to by a State or Veterinary Services Inspector and if such animal is accompanied by a certificate which contains, in addition to the information required in § 75.5(d), the certification by the State or Veterinary Services Inspector that the breeding of the animal was properly performed by artifical insemination.

(5) A mare bred after February 1, 1978, on a known infected premises may move from the quarantined area if it has been determined by a State or Veterinary Services Inspector through epidemiological investigation that she is not an affected or exposed animal and she is accompanied by a certificate;

(6) A mare not bred on a known infected premises may move from the quarantined area if it has been determined by a State or Veterinary Services Inspector through epidemiological investigation that she is not an affected or exposed animal and she is accompanied by a certificate;

(7) A mare or stallion bred on a premises which is not a known infected premises may move from a quarantined area if it has been determined by a State or Veterinary Services Inspector through epidemiological investigation that the animal is not an affected or exposed animal and if the animal is accompanied by a certificate; or

(8) An animal which is not an affected or exposed animal may move interstate through the quarantined area if accompanied by a certificate and if moved through such area without contact with other animals while in such area.

(b) *Movement of animals for immediate slaughter.* (1) No affected or exposed animal shall be moved interstate except for immediate slaughter directly to a Federally inspected slaughtering establishment operated under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or to a State-inspected slaughtering establishment which has inspection by a State inspector at the time of slaughter and only if accompanied by a permit.

(2) An animal other than an affected or exposed animal may be moved interstate for immediate slaughter only if it complies with all of the provisions for movement of affected or exposed animals for slaughter in paragraph (b)(1) of this section.

(c) *Cleaning and disinfection.* Any means of conveyance used to transport an affected or exposed animal interstate shall be thoroughly cleaned and disinfected after such movement in accordance with the provisions of §§ 71.6, 71.7, 71.10, 71.11, and 71.12 of the regulations in this subchapter.

[44 FR 28296, May 15, 1979]

§ 75.10 Procedures for breeding mares to be released from Federal quarantine because of CEM.

(a) Any breeding mare which is affected with or exposed to CEM and which is under Federal quarantine for CEM may be released from Federal quarantine only if the breeding mare has met all the requirements of this section and all specimens required by this section to be submitted to a State or Federal animal disease diagnostic laboratory are cultured and found negative for CEM, except as provided in paragraph (d) of this section.

(b) *Presurgical and surgical requirements.* (1) Within 2 hours prior to surgery required under paragraph (b)(2) of this section, a specimen shall be collected from the clitoral fossa of the breeding mare by an accredited veterinarian and submitted to a State or Federal animal disease diagnostic laboratory for culture.

(2) The clitoral sinuses of the breeding mare shall be removed surgically by an accredited veterinarian.

(3) The clitoral sinuses of the breeding mare shall be placed in a container after removal and received by a State or Federal animal disease diagnostic laboratory for culture within 6 hours of removal.

(c) *Post surgical requirements.* (1) For 5 consecutive days, beginning the seventh day after removal of the clitoral sinuses, an accredited veterinarian shall aseptically clean and wash (scrub) the external genitalia and vaginal vestibule, including the clitoral fossa with a solution of not less than 2 percent chlorhexidine in a detergent base and then fill the clitoral fossa and coat the external genitalia and vaginal vestibule with an ointment of not less than 0.2 percent nitrofurozone.

(2) After an interim of 7 days following the 5th consecutive day of scrubbing the external genitalia and the vaginal vestibule and filling the clitoral fossa:

(i) For any pregnant breeding mare, an accredited veterinarian shall collect three separate specimens from the clitoral fossa at an interval of not less than 7 days between the collection of each specimen and shall submit each specimen to a State or Federal animal disease diagnostic laboratory for culture. Seven days after foaling, an accredited veterinarian shall collect one specimen from the endometrium of the uterus of the breeding mare and one specimen from the foal and each specimen shall be submitted to a State or Federal animal disease diagnostic laboratory for culture. If the foal is female, this specimen shall be collected from the vaginal vestibule and, if male, from the prepuce.

(ii) For any nonpregnant breeding mare for which complement fixation and culture tests for CEM were conducted during the two year-period immediately before the surgery required in this section, and for which records have been kept of all such tests, which disclose that all the tests conducted were negative, an accredited veterinarian shall collect one specimen from the endometrium of the uterus during estrus and shall submit the specimen to a State or Federal animal disease diagnostic laboratory for culture.

(iii) For any nonpregnant breeding mare, other than provided in paragraph (c)(2)(ii) of this section, an accredited veterinarian shall collect three separate sets of specimens from the endometrium of the uterus and clitoral fossa at an interval of not less than 7 days between the collection of each set of specimens with one set of specimens to be collected during estrus and shall submit each specimen to a State or Federal animal disease diagnostic laboratory for culture.

(d) If any specimen required by this section is found to be positive for CEM, the breeding mare shall not be released from Federal quarantine except as provided in this paragraph. For such breeding mare, an accredited veterinarian shall collect three additional separate sets of specimens from the endometrium of the uterus and clitoral fossa at not less than 7-day intervals between each set and shall submit each specimen to a State or Federal animal disease diagnostic laboratory for culture. The third set of specimens shall be collected not less than 1 year from the date of the last positive culture and shall be collected during estrus. If the three additional sets of specimens are all negative for CEM, the breeding mare may be released from Federal quarantine.

[46 FR 15495, Mar. 6, 1981]

PART 76—HOG CHOLERA AND OTHER COMMUNICABLE SWINE DISEASES[1]

GENERAL PROVISIONS

Sec.
76.1 Definitions.
76.2 Notice relating to existence of the contagion or vectors of hog cholera and other swine diseases; prohibition of movement of any hog cholera virus, exceptions; spread of disease through raw garbage; regulations; quarantines.
76.3 General restrictions.
76.4 Interstate movement of hog cholera virus prohibited, except as provided.
76.5 Interstate movement of swine affected with or exposed to hog cholera.
76.6 Interstate movement of certain swine not affected with or exposed to hog cholera.
76.7 Interstate movement of vaccinated swine.
76.8 Interstate movement of swine from a quarantined area.
76.9 Interstate movement of swine products from a quarantined area.
76.10 Movement of swine and swine products from a quarantined area to a nonquarantined area of the same State.
76.11 Movement of swine and swine products through quarantined areas.
76.12 Schedules of restrictions and conditions.
76.13 Interstate movement of specially processed swine products.
76.14 Special processing of swine products.
76.15 Special requirements for interstate movement of swine fed raw garbage and products from swine fed raw garbage.
76.16 Authorization of other movements.
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Sec.
76.18 Approval of livestock markets.
76.19-76.29 [Reserved]
76.30 Cleaning and disinfecting of means of conveyance.
76.31 Cleaning and disinfecting livestock markets and other facilities.
76.32 Disinfectants to be used.

AUTHORITY: Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; sec. 1, 75 Stat. 481; secs. 3 and 11, 76 Stat. 130, 132; 21 U.S.C. 111-113, 114g, 115, 117, 120, 121, 123-126, 134b, 134f.

SOURCE: 37 FR 3600, Feb. 17, 1972, unless otherwise noted.

GENERAL PROVISIONS

§ 76.1 Definitions.

For purposes of this part, the following terms shall have the meanings set forth in this section.

(a) *Administrator.* The Administrator of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or any other official of such Service to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(b) *Deputy Administrator.* The Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, or any other Veterinary Services official to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(c) *Veterinary Services.* Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

(d) *Hog cholera.* The contagious, infectious and communicable disease of swine commonly known as hog cholera.

(e) *Exposed swine.* Any swine that have been in contact with animals known to be or suspected of being affected with hog cholera; any swine which have been inoculated with modified live virus vaccine after January 1, 1970; any swine which have been inoculated with any other virulent hog cholera virus at any time; any swine which have been inoculated with killed or inactivated hog cholera virus vaccine other than as provided in paragraph (w) of this section; or any swine which have been in contact with such vaccinates.

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[1] The functions prescribed in Part 76 of Chapter I, 9 CFR, have been transferred from the Agricultural Research Service, U.S. Department of Agriculture, to the Animal and Plant Health Inspection Service of the Department (36 FR 20707).

(f) *Virulent hog cholera virus.* The living agent capable of causing hog cholera found:

(1) In the clear serum, plasma, defibrinated blood, whole blood or other tissue derived from pigs affected with hog cholera; or

(2) In any material used as a medium for perpetuating such living agent; or

(3) In living hog cholera virus vaccine commonly known as modified live virus vaccine.

(g) *Modified live virus vaccine.* A living hog cholera virus vaccine produced from a modified or attenuated strain of hog cholera virus and prepared under license from the Secretary of Agriculture, issued pursuant to Subchapter E of this chapter.

(h) *Killed or inactivated hog cholera virus vaccine.* A vaccine produced from killed or inactivated hog cholera virus and prepared under license from the Secretary of Agriculture, issued pursuant to Subchapter E of this chapter.

(i) *Garbage.* Waste consisting in whole or in part of animal waste, including any waste animal carcasses or the offal from such carcasses, or parts thereof, but excluding waste from ordinary household operations which is fed directly to swine on the same premises where such household is located.

(j) *Raw garbage.* Garbage that has not been heated throughout to boiling or equivalent temperature (usually 212° F. at sea level) for 30 minutes, or heated according to a method approved in specific cases by the Deputy Administrator[2] as adequate to prevent the spread of hog cholera.

(k) *Food waste.* Edible waste (for animal use) derived from garbage that has been heated throughout to boiling or equivalent temperature (usually 212° F. at sea level) for 30 minutes, or heated according to a method approved in specific cases by the Deputy Administrator[2] as adequate to prevent the spread of hog cholera.

(l) *State.* Any State, Puerto Rico, the United States Virgin Islands, or the District of Columbia.

(m) *Interstate.* From any State into or through any other State.

(n) *Quarantined area.* A State, or portion of a State, quarantined under § 76.2(e) because of hog cholera or other contagious, infectious, or communicable disease of swine.

(o) *Nonquarantined area.* Any State, or portion of a State, not quarantined under this part.

(p) *Person.* Any individual, corporation, company, association, firm, partnership, society, or joint stock company or other legal entity.

(q) *Moved.* Shipped, transported, or otherwise moved, or delivered or received for movement, by any person, by land, water, or air.

(r) *Approved livestock market.* A stockyard, livestock market, buying station, concentration point or any other premises, under State or Federal veterinary supervision where swine are assembled for sale or sale purposes, and which has been approved by the Deputy Administrator under § 76.18.

(s) *Nonapproved livestock market.* A stockyard, livestock market, buying station, concentration point or any other premises, other than an approved livestock market, where swine are assembled for sale or sale purposes.

(t) *Recognized slaughtering establishment.* A slaughtering establishment where State or Federal meat inspection is available.

(u) *Swine product.* Any carcass, part or offal of swine, or product thereof.

(v) *Special processing.* Subjecting a swine product to heat treatment in accordance with the requirements contained in § 76.14.

(w) *Official vaccinates.* Swine which are permanently identified as official vaccinates; were reported at the time of vaccination to the appropriate State or Federal agency; have never received official serum prophylaxis; and were vaccinated against hog cholera prior to July 1, 1969, with a modified live virus hog cholera vaccine approved under this part prior to July 1, 1969, administered in accordance with the recommendations on the vaccine label, or were vaccinated prior to January 1, 1970, with a killed or inactivated hog cholera virus vaccine administered in accordance with the recommendations on the vaccine label.

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[2] Requests for approval of other methods may be made to the Veterinarian in Charge, Animal Health Programs, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, for the State in question.

(x) *Official serum prophylaxis.* The inoculation of swine with anti-hog-cholera serum or hog cholera antibody concentrate, as prescribed in § 76.17, under the supervision of a Federal or State veterinary official, with permanent identification of such swine as having been so inoculated.

(y) *Farm of origin.* A farm where the swine to be shipped interstate were born and which has not been used within the 6 months prior to such shipment to assemble, buy, or sell swine brought in from other sources.

(z) *Slaughter market.* An approved livestock market in a quarantined area, the approval of which has been suspended as provided in § 76.18(c), or an approved livestock market not located within a quarantined area at which swine for sale and shipment for slaughter are handled only on days when no swine are handled for sale and shipment for feeding or breeding purposes, and which is cleaned and disinfected in accordance with the requirements of this part before any swine for feeding or breeding purposes are handled thereat.[3]

(aa)-(bb) [Reserved]

(cc) *Veterinary Services inspector.* A veterinarian or livestock inspector employed by Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, in animal health activities, who is authorized to perform the function involved.

(dd) *State inspector.* A veterinarian or livestock inspector regularly employed in animal health activities by a State or a political subdivision thereof, authorized by such State or political subdivision to perform the function involved under a cooperative agreement with the United States Department of Agriculture.

(ee) *Accredited veterinarian.* An accredited veterinarian as defined in Part 160 of this Chapter.

(ff) *State animal health official.* The State animal health official responsible for livestock and poultry disease control and eradication programs.

(gg) *Veterinarian in charge.* The veterinary official of Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, who is assigned by the Deputy Administrator to supervise and perform the official animal health work of the Animal and Plant Health Inspection Service in the State concerned.

(hh) *Vectors.* Any swine which have been in contact with animals known to be or suspected of being affected with hog cholera and which are or have been introduced into, marketed, or maintained in any State for purposes other than immediate slaughter and therefore may disseminate hog cholera.

[37 FR 3600, Feb. 17, 1972, as amended at 37 FR 26391, Dec. 12, 1972; 39 FR 44404, Dec. 24, 1974; 40 FR 53546, Nov. 19, 1975]

§ 76.2 Notice relating to existence of the contagion or vectors of hog cholera and other swine diseases; prohibition of movement of any hog cholera virus, exceptions; spread of disease through raw garbage; regulations; quarantines.

(a) Notice is hereby given that the contagion or vectors of hog cholera exist in each area specified in paragraph (e) of this section and that the contagion of hog cholera and other communicable diseases of swine may exist in each State.

(b) Notice is hereby given that the Administrator has determined that the prohibition of the interstate movement of any hog cholera virus, except as specified in § 76.4, is necessary in order to effectuate the eradication of hog cholera.

(c) Notice is hereby given that there is reason to believe raw garbage is one of the primary media through which the contagion of hog cholera, swine erysipelas, trichinosis, tuberculosis, and other contagious, infectious, or communicable diseases of swine is disseminated. Further, there is reason to believe that if certain foreign diseases, such as foot-and-mouth disease and African swine fever, gain entrance into the United States, the contagion of such diseases may be spread through the medium of raw garbage. Therefore, the regulations in this part with respect to raw garbage are deemed necessary in order to more effectually prevent, suppress, and extirpate such diseases, to prevent the interstate spread thereof, and to guard against the dissemination of diseases from foreign countries.

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[3] Information concerning slaughter markets can be obtained from the Veterinarian in Charge, Animal Health Programs, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, for the State in question.

(d) Notice is hereby given that in order to effectually suppress and extirpate hog cholera and other contagious, infectious, and communicable diseases of swine, to prevent the spread and dissemination of the contagion thereof and to protect the livestock of the United States, the regulations in this part are promulgated to govern the interstate movement of swine and swine products.

(e) Notice of quarantine: Notice is hereby given that because of the existence of the contagion of hog cholera and the nature and extent of such contagion or the existence of vectors, the following areas are quarantined:

[Reserved]

[37 FR 3600, Feb. 17, 1972]

EDITORIAL NOTE: The quarantined areas in paragraph (e) of § 76.2 are not carried in the Code of Federal Regulations. For Federal Register citations affecting § 76.2, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 76.3 General restrictions.

Swine or swine products referred to in this part shall not be moved interstate except in accordance with the regulations in this part.

§ 76.4 Interstate movement of hog cholera virus prohibited, except as provided.

Virulent hog cholera virus shall not be moved interstate, except that: In specific cases and under such conditions as he may impose to prevent the interstate spread of hog cholera and to effectuate the hog cholera eradication program, the Deputy Administrator may authorize the interstate movement of stated quantities of virulent hog cholera virus for research, diagnostic, biologics production, or export purposes if he determines that such movement will not endanger swine or impair the hog cholera eradication program. When so moved for purposes other than export, such virus shall be accompanied by a permit from the appropriate official of the State of destination and shall in all cases, including export, be accompanied by a certificate issued by the Deputy Administrator specifying any conditions imposed regarding the specific shipment.

§ 76.5 Interstate movement of swine affected with or exposed to hog cholera.

(a) Swine affected with hog cholera may not be moved interstate for any purpose.

(b) Exposed swine (as defined in § 76.1(e)) may be moved interstate from any point in any State to a recognized slaughtering establishment for immediate slaughter and special processing in accordance with Schedule A of § 76.12.

§ 76.6 Interstate movement of certain swine not affected with or exposed to hog cholera.

(a) Swine not known to be affected with or exposed to hog cholera may be moved interstate from any point in any nonquarantined area to a recognized slaughtering establishment for immediate slaughter, or to an approved livestock market for sale for immediate slaughter without further restriction under this part.

(b) Swine not known to be affected with or exposed to hog cholera may be moved interstate from any nonquarantined area for feeding or breeding purposes as provided in this paragraph (b):

(1) From any approved livestock market to any point other than a nonapproved livestock market in accordance with Schedule B of § 76.12.

(2) From a farm of origin to any point other than a nonapproved livestock market in accordance with Schedule C of § 76.12.

(3) From any premises other than a farm of origin or an approved or nonapproved livestock market to any point other than a nonapproved live-

stock market in accordance with Schedule D of § 76.12.

(c) Swine not known to be affected with or exposed to hog cholera may be moved interstate from any nonquarantined area for exhibition purposes as provided in paragraph (b) of this section.

[37 FR 3600, Feb. 17, 1972, as amended at 40 FR 53546, Nov. 19, 1975]

§ 76.7 Interstate movement of vaccinated swine.

(a) Official vaccinates may be moved interstate in accordance with the same restrictions and conditions which apply to nonvaccinated swine under the provisions of this part.

(b) Notwithstanding any other provisions of this part, swine treated with approved modified live virus vaccine after July 1, 1969, but prior to January 1, 1970, or treated with other virulent hog cholera virus prior to April 1, 1966, may be moved interstate only from a nonquarantined area and if they are not known to be affected with or otherwise exposed to hog cholera and are consigned to a recognized slaughtering establishment for immediate slaughter.

§ 76.8 Interstate movement of swine from a quarantined area.

Swine may be moved interstate from a quarantined area in accordance with the provisions of this section.

(a) Exposed swine (as defined in § 76.1(e)) may be moved interstate as provided in § 76.5(b).

(b) Swine not known to be affected with or exposed to hog cholera may be moved interstate from a quarantined area as provided in this paragraph only for immediate slaughter or for sale and shipment for immediate slaughter. Such swine may be so moved interstate:

(1) From any point other than an approved or nonapproved livestock market to a recognized slaughtering establishment or to a slaughter market (as defined in § 76.1(z)) in accordance with Schedule E of § 76.12.

(2) From a slaughter market (as defined in § 76.1(z)) to a recognized slaughtering establishment in accordance with Schedule E of § 76.12.

(c) *Quarantine of swine or detention of swine products moving interstate in violation of regulations.* The Deputy Administrator may order the quarantine of swine or the detention of swine products found to be moving interstate in violation of regulations contained in this part. Release from quarantine or other disposition of such quarantined swine or release of swine products detained to prevent the spread of disease will be subject to the requirement of special processing in accordance with § 76.14 or any other conditions which may be specified by the Deputy Administrator as necessary to prevent the spread of hog cholera or other communicable diseases of livestock. Except for supervision, no expense incurred in quarantining or otherwise disposing of quarantined swine or in detaining or disposing of detained swine products will be borne by the Department of Agriculture.

[37 FR 3600, Feb. 17, 1972, as amended at 40 FR 53546, Nov. 19, 1975]

§ 76.9 Interstate movement of swine products from a quarantined area.

Swine products not derived from swine affected with or exposed to hog cholera may be moved interstate from a quarantined area if they were produced in a federally inspected slaughtering establishment operating under the provisions of the Federal Meat Inspection Act, as amended (21 U.S.C. 601 et seq.).

§ 76.10 Movement of swine and swine products from a quarantined area to a nonquarantined area of the same State.

Swine and swine products moved from the quarantined area of a State to a nonquarantined area of the same State may be moved interstate only as specified in §§ 76.8 and 76.9.

§ 76.11 Interstate movement of swine and swine products through quarantined areas.

Swine and swine products may be moved interstate from nonquarantined areas through quarantined areas without compliance with §§ 76.8 and 76.9 if (a) such movement is continuous and direct and such swine and swine products are not unloaded in the quarantined areas; or (b) if all facilities used in connection with the unloading have been approved for such purpose by a Veterinary Services inspector as having been cleaned and disinfected before such use, as prescribed in §§ 76.30 through 76.32, under the supervision of a person authorized for the purpose by the inspector.

§ 76.12 Schedules of restrictions and conditions.[4]

SCHEDULE A

Schedule A applies to the interstate movement of swine for immediate slaughter and special processing as provided in §§ 76.5(b) and 76.15 and requires that:

1. The swine must be moved to a recognized slaughtering establishment for immediate slaughter and special processing.
2. The recognized slaughtering establishment must be designated by the Deputy Administrator to slaughter specific shipments of exposed swine.
3. The means of conveyance must be sealed during transit with Department seals or accompanied by a representative of Veterinary Services or a person specifically authorized for the purpose by the Deputy Administrator.
4. The seals must not be removed or broken except by a meat inspector employed by the Consumer and Marketing Service of the U.S. Department of Agriculture or other persons specifically authorized for this purpose by the Deputy Administrator.
5. The swine must be accompanied by a certificate of a Veterinary Services inspector showing that the establishment to which the animals are consigned has been specifically approved by the Deputy Administrator, that the inspector has inspected all swine on the premises of origin within 48 hours of shipment interstate, and that the swine are apparently free of hog cholera and other contagious, infectious, or communicable diseases.

SCHEDULE B

Schedule B applies to the interstate movement of feeder and breeder swine as provided in § 76.6(b)(1) and requires that:

1. The interstate movement must be continuous.
2. The interstate movement must be in the same means of conveyance in its entirety.
3. The swine must be inspected by a Veterinary Services or State inspector or an accredited veterinarian at the point of origin of the interstate shipment immediately prior to such shipment, and found to be apparently free of hog cholera and other contagious, infectious, or communicable diseases.
4. The swine must be accompanied by an inspection certificate issued by the Veterinary Services or State inspector or accredited Veterinarian showing:
   (a) Place and date of issuance.
   (b) Consignee and consignor.
   (c) That the swine have been inspected by the Veterinary Services or State inspector or accredited veterinarian, and are apparently free of hog cholera and other contagious, infectious, or communicable diseases.
5. A copy of the inspection certificate must be forwarded to the appropriate Animal Health official of the State of destination.
6. Swine moved from an approved livestock market must be transported in a means of conveyance which has been cleaned and disinfected as provided in §§ 76.30 and 76.32; *Provided, however,* That if the means of conveyance is not regularly used to transport livestock, disinfection is not required.

SCHEDULE C

Schedule C applies to the interstate movement of feeder and breeder swine as provided in § 76.6(b)(2) and requires that:

1. The interstate movement must be continuous.
2. The interstate movement must be in the same means of conveyance in its entirety.

SCHEDULE D

Schedule D applies to the interstate movement of feeder and breeder swine as provided in § 76.6(b)(3) and requires that:

1. The interstate movement must be continuous.
2. The interstate movement must be in the same means of conveyance in its entirety.
3. The swine must be inspected by a Veterinary Services or State inspector or accredited Veterinarian at the point of origin of the interstate shipment immediately prior to such shipment and found to be apparently free of hog cholera and other contagious, infectious, or communicable diseases.
4. The swine must be accompanied by an inspection certificate issued by the Veterinary Services or State inspector or accredited veterinarian showing:
   (a) Place and date of issuance.
   (b) Consignee and consignor.
   (c) That the swine have been inspected by the Veterinary Services or State inspector

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[4] In each instance the regulations of the State of destination should be consulted.

or accredited veterinarian and are apparently free from hog cholera and other contagious, infectious, or communicable diseases.

5. A copy of the inspection certificate must be forwarded to the appropriate Animal Health official of the State of destination.

Schedule E

Schedule E applies to the movement of swine from a quarantined area for slaughter purposes as provided in § 76.8(b) and requires that:

1. A permit for the movement must be obtained from the appropriate Animal Health official of the State of destination.

2. (a) The swine must be identified by an individual ear tag to the premises of origin or by a red mark at least 4" × ½" above the shoulder on the back of each animal, or (b) the means of conveyance in which the swine are moved interstate must be sealed with Department seals.

3. If the means of conveyance is sealed, the seals must not be removed or broken except by a meat inspector employed by the Consumer and Marketing Service of the U.S. Department of Agriculture or by other persons authorized for this purpose by the Deputy Administrator.

4. All swine on the premises of origin, including the swine to be moved interstate, must be inspected on the premises of origin by a Veterinary Services or State inspector or an accredited veterinarian within 24 hours prior to the time the interstate movement is to begin and all swine on the premises must be found to be apparently free of hog cholera and other contagious, infectious and communicable diseases, and known exposure thereto.

5. The swine must be moved for immediate slaughter directly to a federally inspected slaughtering establishment operating under the provisions of the Federal Meat Inspection Act, as amended (21 U.S.C. 601 et seq.), or to a State inspected slaughtering establishment which has inspection by a State inspector at the time of slaughter; or to a slaughter market (as defined in § 76.1(z) for sale and shipment for immediate slaughter; they must be moved without contact at any point with feeding or breeding swine; they shall not be unloaded en route; and they shall not be diverted.

6. The swine must be accompanied by an inspection certificate issued by a Veterinary Services or State inspector or an accredited veterinarian showing:

(a) That all swine on the premises of origin, including those covered by the certificate, were inspected by him as prescribed in paragraph 4 of this Schedule E and found to be apparently free from hog cholera and other contagious diseases and from known exposure thereto.

(b) Consignee and consignor.

(c) Number of swine covered by the certificate.

(d) The individual eartag identification numbers of the swine or the existence of the red color mark on each animal covered by the certificate as prescribed in paragraph 2 of this Schedule E.

(e) That the swine covered by the certificate must be moved directly to the federally or State inspected slaughtering establishment or slaughter market specified on the certificate.

(f) That the swine must be moved without contact at any point with feeding or breeding swine and shall not be unloaded or diverted enroute.

7. A copy of the inspection certificate must be forwarded to the appropriate Animal Health official of the State of destination.

8. The means of conveyance used to transport the swine interstate must be placarded by affixing conspicuously thereto a durable placard not less than 5 x 8 inches in size on which are printed in block bold faced letters not less than 1½ inches in height, the words "Swine For Slaughter Only."

9. The means of conveyance must be cleaned and disinfected in accordance with §§ 76.30 and 76.32 under supervision by a Veterinary Services or State inspector immediately following unloading, except that the Deputy Administrator may, in specific cases, approve other points for such cleaning and disinfection when he finds that such procedure will not hamper the hog cholera eradication program.

[37 FR 3600, Feb. 17, 1972, as amended at 40 FR 53547, Nov. 19, 1975]

§ 76.13 Interstate movement of specially processed swine products.

Except as provided in §§ 76.9, 76.10, 76.11, and 76.15, swine products which have been specially processed may be moved interstate without restriction under this part.

§ 76.14 Special processing of swine products.

All swine products required under the regulations of this part to be specially processed shall be heated to an internal temperature of at leasts 156° F. for 30 minutes or to an internal temperature of 177° F. for 3 minutes.

§ 76.15 Special requirements for interstate movement of swine fed raw garbage and products from swine fed raw garbage.

(a) *Movement of swine.* Swine which have been fed any raw garbage may be moved interstate under this part only in accordance with Schedule A of § 76.12 to a slaughtering establishment specifically approved for the purpose by the Deputy Administrator in each case, for immediate slaughter and special processing at such establishment in a manner approved by the Deputy Administrator as adequate to prevent the spread of communicable livestock diseases.

(b) *Movement of swine products.* (1) Swine products produced at an establishment operating under the Federal Meat Inspection Act, as amended (21 U.S.C. 601 et seq.), which handles products of swine fed raw garbage but specially processes all such products separate and apart from other swine products, keeps the products properly identified and otherwise handles the products in a manner approved by the Deputy Administrator as adequate to prevent the spread of communicable livestock diseases, may be moved interstate without further restriction under this section, but in accordance with the other provisions of this part.

(2) Swine products produced at an establishment operating under the Federal Meat Inspection Act, as amended (21 U.S.C. 601 et seq.), which handles any products of swine fed any raw garbage and does not handle all such products as specified in paragraph (b) (1) of this section, may be moved interstate only if accompanied by a certificate signed by a meat inspector of the Consumer and Marketing Service, U.S. Department of Agriculture (i) identifying the products to be moved interstate and stating that, insofar as he has been able to determine, the particular products were derived from swine which had not been fed any raw garbage, or (ii) identifying the products to be moved interstate and stating that the particular products have been handled as specified in paragraph (b)(1) of this section.

§ 76.16 Authorization of other movements.

The Deputy Administrator, in specific cases, may authorize the interstate movement of swine or swine products not otherwise authorized under this part, under such conditions as he may prescribe to prevent the spread of hog cholera or other contagious, infectious, or communicable diseases, and when so moved, the swine or swine products must be accompanied by a permit from the appropriate Animal Health official of the State of destination and a permit from Veterinary Services specifying any conditions imposed regarding such movement.

§ 76.17 Serum prophylaxis treatment of swine.

Although there is no requirement under this part that swine be treated with anti-hog-cholera serum or hog cholera antibody concentrate prior to interstate movement, if swine do receive serum prophylaxis prior to interstate movement they shall be inoculated with anti-hog-cholera serum or hog cholera antibody concentrate prepared under license from the Secretary of Agriculture issued pursuant to Subchapter E of this chapter; they shall meet all other applicable provisions of this part; and the permitted dosage of anti-hog-cholera serum or hog cholera antibody concentrate shall be as follows:

Weight of swine (pounds)	Minimum dose of serum (cubic centimeters)	Minimum dose of antibody concentrate (cubic centimeters)
Under 20		
20		10
20 to 40	30	15
40+ to 90	35	18
90+ to 120	45	23
120+ to 150	55	28
150+ to 180	65	33
Over 180	75	38

NOTE: Except for swine under 30 pounds in weight, the dosage of serum should not exceed 1 cc. per pound body weight, or one-half cc. per pound body weight if antibody concentrate is used.

§ 76.18 Approval of livestock markets.

(a) Notices containing lists of livestock markets approved for the purposes of the regulations in this part will be published in the FEDERAL REG-

ISTER. Information with respect to those livestock markets may also be obtained from Veterinary Services.

(b) The Deputy Administrator is authorized to approve any livestock market for the purposes of the regulations in this part when he determines that the operator of such livestock market has executed an appropriate agreement as set forth in paragraph (b) (1) or (2) of this section and that the livestock market meets the standards specified in such agreement. Request for such approval may be made to the Veterinarian in Charge, Animal Health Programs, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, for the State in which the livestock market is located, and the executed agreement shall be filed with said Veterinarian in Charge. The Deputy Administrator is authorized to promulgate notices listing approved livestock markets in accordance with paragraph (a) of this section. The Deputy Administrator may withdraw approval and remove any livestock market from such list when he determines that such livestock market no longer complies with the requirements of the agreement applicable to its operations, or that the operator has terminated such agreement.[5]

(1)

AGREEMENT FOR APPROVAL TO HANDLE INTERSTATE SHIPMENTS OF ANY CLASS OF SWINE

To: Veterinary Services Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

The undersigned operator of the livestock market known as ———————— (Name) located at ———————— (Address), hereby requests approval to handle interstate shipments of feeder or breeder and/or slaughter swine in accordance with the regulations in 9 CFR 76. Said operator agrees to:

1. Provide Veterinary Services with a schedule of sale days and cooperate with Veterinary Services in obtaining compliance by livestock shippers with applicable State and Federal regulations.

2. Provide well-constructed and well-lighted imperviously surfaced pens, alleys, and sales rings for holding, inspecting and otherwise handling swine, and keep all swine handling facilities clean and in good repair.

3. Require all swine received at the livestock market to be given an inspection by a Veterinary Services or State inspector or an accredited veterinarian, and refuse to sell any swine that show signs of any infectious, contagious, or communicable disease upon such inspection except as authorized by a Veterinary Services or State inspector or an accredited veterinarian.

4. Separate from the other swine all swine found upon inspection to be, or suspected of being, affected with any contagious, infectious, or communicable disease and immediately notify a Veterinary Services or State inspector, or an accredited veterinarian, of the presence of such swine at the livestock market.

5. Permit no feeder or breeder swine to remain in the livestock market for more than 72 hours and permit no slaughter swine to remain in the livestock market for more than 120 hours.

6. Issue no release for removal of feeder or breeder swine from the livestock market until the swine are identified in accordance with applicable requirements of Federal or State regulations and have been inspected by a Veterinary Services or State inspector, or an accredited veterinarian, and certified in accordance with applicable Federal or State regulations.

7. Issue no release for removal of slaughter swine from the livestock market unless consigned for immediate slaughter and identify the consignee on the release document.

8. Clean and disinfect pens, alleys, sales rings, docks, scales, and other facilities when required under §§ 71.4 or 76.31, with a disinfectant specified in § 76.32.

9. Provide facilities and services for cleaning and disinfecting means of conveyance as prescribed in §§ 76.30 and 76.32.

10. Permit no swine to be inoculated at the livestock market with any hog cholera vaccine or any virulent hog cholera virus.

11. Maintain, for one year after the transaction involved, a record of the origin and destination of all swine, and also of the identification of all swine required to be identified in accordance with Paragraph 6 of this agreement, handled through the livestock market and afford Veterinary Services and State inspectors access to such records at all reasonable times.

(Name of operator of livestock market) ——
(Address) ————————————
(Signature and Title) ————————
(Date) ————————————

The Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, has approved this application effective ———— (Date).

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[5] The standards contained in these agreements are minimal and agreements within individual States may be adjusted to conform to more restrictive State laws or regulations.

(Veterinarian in Charge) ————
(Address) ————
(Date) ————

(2) See the following example:

AGREEMENT FOR APPROVAL TO HANDLE INTERSTATE SHIPMENTS OF SLAUGHTER SWINE

To: Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture:

The undersigned operator of the livestock market known as ———— (Name), located at ———— (Address), hereby requests approval to handle interstate shipments of slaughter swine only, in accordance with the regulations in 9 CFR, Part 76. Said operator agrees to:

1. Provide Veterinary Services with a schedule of sale days and cooperate with Veterinary Services in obtaining compliance by livestock shippers with applicable State and Federal regulations.
2. Separate from other swine all swine suspected of being affected with any contagious, infectious, or communicable disease and immediately notify a Veterinary Services or State inspector, or an accredited veterinarian, of the presence of such swine at the livestock market.
3. Issue no releases for removal of any swine from the livestock market unless consigned for immediate slaughter and identify the consignee on the release document.
4. Permit no swine to be inoculated at the livestock market with any modified live virus hog cholera vaccine or any other virulent hog cholera virus.
5. Maintain, for one year after the transaction involved, a record of the origin and destination of all swine handled through the livestock market and afford Veterinary Services and State inspectors access to such records at all reasonable times.

(Name of operator of livestock market) ————
(Address) ————
(Signature and title) ————
(Date) ————

The Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, has approved this application effective ———— (Date).

(Veterinarian in charge) ————
(Address) ————
(Date) ————

(c) *Approval of livestock markets in a quarantined area.* The approved status of all livestock markets approved for the purposes of the regulations in this part under this section which are located in an area placed under quarantine because of hog cholera, shall be suspended (only for purposes of this part) when such area is placed under quarantine and shall be restored when such area is released from quarantine only upon compliance with all provisions of this section: *Provided,* That such livestock markets which qualify under § 76.1(z) may operate as slaughter markets for the purpose of receiving interstate shipments of slaughter swine and releasing in accordance with § 76.8, directly to a slaughter swine for interstate shipment, federally inspected slaughtering establishment operating under the provisions of the Federal Meat Inspection Act, as amended (21 U.S.C. 601 et seq.), or to a State inspected slaughtering establishment which has inspection by a State inspector at the time of slaughter.

(Approved by the Office of Management and Budget under control number 0579-0016)

[37 FR 3600, Feb. 17, 1972, as amended at 40 FR 53547, Nov. 19, 1975; 48 FR 57472, Dec. 30, 1983]

§§ 76.19—76.29 [Reserved]

§ 76.30 Cleaning and disinfecting of means of conveyance.

(a) All means of conveyance and their associated equipment used for receiving, shipping, loading, unloading, and delivering swine and for feeding, watering, and resting swine, in connection with the interstate movement of swine, shall be kept clean.

(b) Any means of conveyance and its associated equipment which has been used to move swine interstate which are affected with any contagious, infectious, or communicable disease, shall be cleaned and disinfected under the supervision of a Veterinary Services or State inspector or an accredited veterinarian as follows: Remove all litter, feed, and manure from all portions of each means of conveyance, including all ledges and framework inside and outside, and handle such litter, feed, and manure in such manner as not to expose livestock to any disease contained therein; clean the interior and the exterior of such vehicle or other means of conveyance and its associated equipment; and saturate the entire interior surface, including all doors, endgates, portable chutes, and similar equipment with a disinfectant prescribed in § 76.32.

(c) The Deputy Administrator may, in specific cases, require the thorough cleaning and disinfecting, under the supervision of a Veterinary Services or State inspector or an accredited veterinarian in the manner provided in paragraph (b) of this section, of any means of conveyance which has been used to move interstate any swine which have been fed any raw garbage, or any swine products derived from such swine, or swine exposed to hog cholera or other contagious, infectious or communicable livestock disease, or which the Deputy Administrator has reason to believe may have been otherwise infected with or exposed to such a disease, when he determines that such cleaning and disinfecting is necessary to guard against the spread of any such disease.

(d) The carrier shall be responsible for cleaning and disinfecting all means of conveyance and associated equipment as required by this section and such cleaning and disinfecting shall be done without expense to the Department of Agriculture.

(e) Such cleaning and disinfecting shall be done before the means of conveyance is moved from the place where the swine or swine products are unloaded, unless the Deputy Administrator, in specific cases, authorizes its movement to another location and cleaning and disinfecting is carried out at such location in accordance with this section.

§ 76.31 Cleaning and disinfecting livestock markets and other facilities.

(a) All livestock markets and other facilities, including facilities for receiving, shipping, loading, unloading, and delivering swine and for feeding, watering, and resting swine, used in connection with the interstate movement of swine shall be kept clean.

(b) All livestock markets and other facilities, or any portion thereof, which have been used in connection with the interstate movement of swine which are affected with any contagious, infectious, or communicable disease, shall be cleaned and disinfected under the supervision of a Veterinary Services or State inspector or an accredited veterinarian as follows: Empty all troughs and other feeding and watering appliances; remove all litter, feed, and manure from the floors, posts, or other parts, and handle such litter, feed, and manure in such manner as not to expose livestock to any disease contained therein; and saturate the entire surface of the fencing, troughs, chutes, floors, walls, and all other parts with a disinfectant as prescribed in § 76.32.

(c) The Deputy Administrator, in specific cases, may require the thorough cleaning and disinfecting, under the supervision of a Veterinary Services or State inspector or an accredited veterinarian, in the manner provided in paragraph (b) of this section, of any livestock market and other facility, or any portion thereof, which has been used in connection with the interstate movement of any swine which have been fed any raw garbage or swine products derived from such swine, or swine exposed to hog cholera or other contagious, infectious, or communicable disease, or which the Deputy Administrator has reason to believe may have been otherwise infected with or exposed to such a disease, when he determines that such cleaning and disinfecting is necessary to guard against the spread of any such disease.

(d) The owner of such livestock markets and other facilities shall be responsible for cleaning and disinfecting as required under this section, and the cleaning and disinfecting shall be done without expense to the Department of Agriculture.

(e) All livestock markets or other facilities, or any portion thereof, required to be cleaned and disinfected under this section shall not be used for handling swine until after the cleaning and disinfecting has been done.

§ 76.32 Disinfectants to be used.

Disinfection required under the regulations in this part shall be performed with one of the following:

(a) A permitted brand of sodium orthophenylphenate used in a proportion of at least 1 pound to 12 gallons of water, as prescribed in § 71.12 of this chapter.

(b) A permitted cresylic disinfectant in the proportion of at least 4 fluid ounces to 1 gallon of water, as prescribed under §§ 71.10(b) and 71.11 of this chapter.

(c) A permitted general disinfectant (which meets the specifications of § 71.10(a)(5) of this chapter) and which has been shown to be virucidal against the virus of hog cholera, as determined by the Deputy Administrator,[6] may be used at the dilution and otherwise in accordance with directions for use as shown on the label of such disinfectant.

PART 77—TUBERCULOSIS IN CATTLE

Subpart A—General Provisions

Sec.

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77.3 Designation of States or areas.
77.4 Accredited-free States.
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Subpart B—Interstate Movement of Cattle Not Known To Be Affected With or Exposed to Tuberculosis

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77.9 Movement from accredited-free States, modified accredited areas, and nonmodified accredited areas.
77.10 Other movements.

AUTHORITY: 21 U.S.C. 111, 114, 114a, 115-117, 120, 121, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 43 FR 34431, Aug. 4, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 77.1 Definitions.

As used in this part, the following terms shall have the meanings set forth in this section except as otherwise specified.

(a) *Animal.* All species of animals except man, birds, or reptiles.

(b) *Cattle.* Domestic bovine animals of all ages.

(c) *Tuberculosis.* The contagious, infectious, and communicable disease of cattle caused by *Mycobacterium bovis.*

(d) *Uniform Methods and Rules—Bovine Tuberculosis Eradication.* Uniform methods and rules for the establishment and maintenance of tuberculosis-free accredited herds of cattle, modified accredited areas, and areas accredited-free of bovine tuberculosis in the domestic bovine, as adopted by the United States Animal Health Association on October 19, 1977, and approved by Veterinary Services effective December 22, 1977. The provisions of the Uniform Methods and Rules—Bovine Tuberculosis Eradication are hereby incorporated by reference [1], and are the minimum standards for achieving and maintaining herd and area status.

(e) *Official tuberculin test.* Any intradermal test for tuberculosis conducted in accordance with the Uniform Methods and Rules—Bovine Tuberculosis Eradication.

(f) *Negative cattle.* Cattle classified negative to an official tuberculin test in accordance with the guidelines established in part II, G., 3., b., of the Uniform Methods and Rules—Bovine Tuberculosis Eradication.

(g) *Suspect cattle.* Cattle responding to an official tuberculin test and classified suspect in accordance with the guidelines established in part II, G., 2., of the Uniform Methods and Rules—Bovine Tuberculosis Eradication.

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[6] Information as to the names of such disinfectants may be obtained from the Veterinarian in Charge or a Veterinary Services inspector.

[1] Copies of the Uniform Methods and Rules—Bovine Tuberculosis Eradication are available upon request from Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, Hyattsville, Md. 20782, and were filed as part of this original document.

(h) *Reactor cattle.* Cattle responding to an official tuberculin test and classified reactor in accordance with the guidelines established in part II, G., 1., of the Uniform Methods and Rules—Bovine Tuberculosis Eradication.

(i) *Herd.* Any group of cattle maintained on common ground for any purpose, or two or more groups of cattle under common ownership or supervision, which are geographically separated, but among which there is an interchange or movement of cattle without regard to health status.

(j) *Affected herd.* A herd of cattle in which tuberculosis has been disclosed in any such cattle by an official tuberculin test or by postmortem examination.

(k) *Cattle not known to be affected.* All cattle except those originating from tuberculosis affected herds or from herds containing tuberculosis suspect cattle.

(l) *Exposed cattle.* Cattle, except reactor cattle, which are part of an affected herd.

(m) *Department.* The U.S. Department of Agriculture (USDA).

(n) *Veterinary Services.* The Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

(o) *Deputy Administrator.* The Deputy Administrator, Veterinary Services, or any other Veterinary Services official to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(p) *State.* Any State, territory, the District of Columbia, or Puerto Rico.

(q) *Interstate.* From one State into or through any other State.

(r) *Moved.* Shipped, transported, or otherwise moved, or delivered or received for movement.

(s) *Person.* Any individual, corporation, company, association, firm, partnership, society, or joint stock company, or other legal entity.

(t) *Veterinary Services representative.* A veterinarian or other person employed by Veterinary Services who is authorized to perform the function involved.

(u) *State representative.* A veterinarian or other person employed in livestock sanitary work of a State or political subdivision thereof and who is authorized by such State or political subdivision thereof to perform the function involved under a memorandum of understanding with the Department.

(v) *Accredited veterinarian.* An accredited veterinarian as defined in part 160 of this chapter.

(w) *Modified accredited area.* A State or portion thereof which complies with all of the procedures in part X of the Uniform Methods and Rules—Bovine Tuberculosis Eradication.

(x) *Nonmodified accredited area.* A State or any portion thereof which has not received accredited-free State or modified accredited area status.

(y) *Accredited-free State.* A State which complies with all of the procedures of part XI of the Uniform Methods and Rules—Bovine Tuberculosis Eradication.

(z) *Accredited herd.* A cattle herd which meets the requirements of part IX of the Uniform Methods and Rules—Bovine Tuberculosis Eradication.

(aa) *Certificate.* An official document issued by a Veterinary Services representative, a State representative, or an accredited veterinarian at the point of origin of a shipment of cattle to be moved under this part, which shows the identification tag, tattoo, or registration number or similar identification of each animal to be moved, the number, breed, sex, and approximate age of the animals covered by the document, the purpose for which the animals are to be moved, the date and place of issuance, the points of origin and destination, the consignor, and the consignee, and which states that the animal or animals identified on the certificate meet the requirements of this part.

(bb) *Permit.* An official document issued for movement of animals under this part by a Veterinary Services representative, State representative, or an accredited veterinarian at the point of origin of a shipment of cattle to be moved directly to slaughter, which shows the tuberculosis status of each animal (reactor, suspect, or exposed), the ear tag number of each animal and the name of the owner of such animal, the establishment to which the animals are to be moved, the purpose for which the animals are to be moved and that they are eligible for such movement under the applicable provisions of §§ 77.9 and 77.10.

(cc) *Transportation document.* Any document accompanying the interstate movement, such as an owner's statement, manifest, switch order, or vehicle record, on which is stated: (1) The point from which the animals are moved interstate; (2) the destination of the animals; (3) the number of animals covered by the document; and (4) the name and address of the owner or shipper.

(dd) *Official seal.* A seal issued by a State or Veterinary Services representative.

§ 77.2 General restrictions.

Cattle may not be moved interstate except in compliance with the regulations in this part.

§ 77.3 Designation of States or areas.

The Deputy Administrator may amend the regulations in this part to designate States or portions thereof as modified accredited areas, accredited-free States, or nonmodified accredited areas, respectively, when he determines that these States or portions thereof come within the appropriate definitions in § 77.1 (w), (x), or (y), and to delete any State or portion thereof from any such list at any time when he determines that they no longer come within the appropriate definition.

§ 77.4 Accredited-free States.

(a) Accredited-free State status shall have a duration of 1 year. In order to qualify for reaccreditation, such States shall annually, between October 1 and November 30, submit a report to Veterinary Services certifying that the State is in compliance with all the requirements of Part XI of the Uniform Methods and Rules—Bovine Tuberculosis Eradication regarding accredited-free States.

(b) The following States are hereby designated accredited-free States: Arizona, Colorado, Connecticut, Delaware, Indiana, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Wyoming, and the Virgin Islands of the United States.

[43 FR 34431, Aug. 4, 1978, and amended at 50 FR 51836, Dec. 20, 1985]

EFFECTIVE DATE NOTE: Paragraph (b) of § 77.4 was revised at 50 FR 51836, Dec. 20, 1985, effective January 21, 1986. For the convenience of the user the superseded text is set forth below.

§ 77.4 Accredited-free States.

* * * * *

(b) The following States are hereby designated accredited-free States: Colorado, Connecticut, Maine, Maryland, Minnesota, Montana, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Rhode Island, Utah, and Wyoming.

§ 77.5 Modified accredited areas.

(a) Modified accredited area status shall have a duration of 1 year. In order to qualify for reaccreditation, such States shall annually, between October 1 and November 30, submit a report to Veterinary Services certifying that the State is in compliance with all the requirements of Part X of the Uniform Methods and Rules—Bovine Tuberculosis Eradication regarding modified accredited areas.

(b) The following States or portions thereof are hereby designated as modified accredited areas: All States or portions thereof except those otherwise designated in § 77.4 or § 77.6.

§ 77.6 Nonmodified accredited areas.

The following States or portions thereof are hereby designated as nonmodified accredited areas:

[No States].

Subpart B—Interstate Movement of Cattle Not Known To Be Affected With or Exposed To Tuberculosis

§ 77.7 Movement from accredited-free States and modified accredited areas.[3]

Cattle not known to be affected with or exposed to tuberculosis, originating in an accredited-free State or a modified accredited area, may be moved interstate without restriction.

§ 77.8 Movement from nonmodified accredited areas.

Cattle not known to be affected with or exposed to tuberculosis, originating in a nonmodified accredited area, shall only be moved interstate if:

(a) Such cattle are accompanied by a certificate stating that such cattle have been classified negative to an official tuberculin test, which was conducted within 30 days prior to the date of movement. All cattle not individually identified by a registration name and number shall be individually identified by a Veterinary Services approved metal eartag or tattoo; or

(b) Such cattle are from an accredited herd and they are accompanied by a certificate showing the cattle to be from such a herd; or

(c) Such cattle are moved interstate directly to slaughter to an establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or to a State inspected slaughtering establishment which has inspection by a State inspector at the time of slaughter.

Subpart C—Interstate Movement of Cattle Affected With or Exposed to Tuberculosis

§ 77.9 Movement from accredited-free States, modified accredited areas, and nonmodified accredited areas.

(a) *Reactor cattle.* Cattle which have been classified as reactor cattle may be moved interstate only if they are moved directly to slaughter at an establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or to a State-inspected slaughtering establishment which has inspection by a State inspector at the time of slaughter, and only upon compliance with the following conditions:

(1) The reactor cattle shall be individually identified by branding the letter "T" not less than 2 nor more than 3 inches high on the left jaw and by a Veterinary Services approved metal eartag bearing a serial number and the inscription "U.S. Reactor" or a similar State reactor tag bearing such number and similar description attached to the left ear of each animal; and

(2) The reactor cattle shall be accompanied by a permit; and

(3) The reactor cattle shall not be moved interstate in a means of conveyance containing any animals susceptible to tuberculosis unless all of the animals are being moved directly to slaughter; and

(4) Any person who moves reactor cattle interstate under this paragraph shall plainly write or stamp upon the face of the transportation document the words "Tuberculin Reactor" and the following statement: "This conveyance shall be cleaned and disinfected in accordance with § 77.9(a)(5) of the regulations."; and

(5) Each means of conveyance in which reactor cattle have been transported interstate under this paragraph shall be cleaned and disinfected by the carrier, in accordance with the provisions of §§ 71.6, 71.7, and 71.10 of this subchapter, under the supervision of a Veterinary Services representative or State representative or an accredited veterinarian or other person designated by the Deputy Administrator. If, at the point where the cattle are unloaded, such supervision or proper cleaning and disinfecting facilities are not available, and permission is obtained from a Veterinary Services representative or State representative, the empty means of conveyance may be moved to a location where such supervision and facilities are available for cleaning and disinfecting. Permission shall be granted if such movement does not present a risk of the dissemination of tuberculosis.

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[3] The regulations of the State of destination should be consulted before shipments are made from accredited-free State and modified accredited areas.

(b) *Exposed cattle.* Cattle which have been classified as exposed cattle shall be moved interstate only if they are moved directly to slaughter to an establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or to a State inspected slaughtering establishment which has inspection by a State inspector at the time of slaughter and only in compliance with the following conditions:

(1) Such exposed cattle must be individually identified by branding the letter "S" not less than 2 nor more than 3 inches high on the left jaw and by tagging with a Veterinary Services approved metal eartag bearing a serial number attached to either ear of each animal, except that in lieu of branding, the cattle may be accompanied to slaughter by a Veterinary Services representative or State representative, or may be moved in vehicles closed with official seals. When such cattle are moved in vehicles closed with official seals, said seals shall only be removed by a State or Federal employee specifically designated by the Deputy Administrator; and

(2) Such exposed cattle shall be moved in accordance with the requirements pertaining to reactor cattle contained in paragraphs (a)(2), (a)(3), and (a)(5) of this section.

(c) *Suspect cattle.* Suspect cattle which have not been retested and found negative from herds in which no reactor cattle have been disclosed on an official tuberculin test, and negative cattle from such herds, shall only be moved interstate if they are moved directly to slaughter to an establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or to a State inspected slaughtering establishment which has inspection by a State inspector at the time of slaughter.

§ 77.10 Other movements.

The Deputy Administrator may, with the concurrence of the livestock sanitary officials of the State of destination, upon request in specific cases, permit the movement of cattle not otherwise provided for in this part which have not been classified as reactor cattle and are not otherwise known to be affected with tuberculosis, under such conditions as he may prescribe in each specific case to prevent the spread of tuberculosis. The Deputy Administrator shall promptly notify the appropriate livestock sanitary officials of the State of destination of any such action. The revision of the regulations imposes certain restrictions necessary to prevent the interstate spread of tuberculosis in cattle. It does not appear that further public participation in this rulemaking proceeding would make additional relevant information available to the Department.

PART 78—BRUCELLOSIS

Subpart A—General Provisions

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AUTHORITY: 21 U.S.C. 111-114a-1, 114g, 115, 117, 120, 121, 123-126, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 40 FR 17816, Apr. 22, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 78.1 Definitions.

As used in this part, the following terms shall have the meanings set forth in this section except as otherwise specified.

(a) *Brucellosis.* The contagious, infectious, and communicable disease caused by bacteria of the genus Brucella. It is also known as Bangs disease, undulant fever, and contagious abortion.

(b) *Veterinary Services.* Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture.

(c) *Deputy Administrator.* The Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, or any other Veterinary Services official to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(d) *Veterinarian in Charge.* The veterinary official of Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, who is assigned by the Deputy Administrator to supervise and perform the official animal health work of the Animal and Plant Health Inspection Service in the State concerned.

(e) *Veterinary Services representative.* A veterinarian or other person employed by Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, who is authorized to perform the function involved.

(f) *State animal health official.* The State animal health official responsible for livestock and poultry disease control and eradication programs.

(g) *State representative.* A veterinarian or other person regularly employed in livestock sanitary work of a State or a political subdivision thereof, and who is authorized by such State or political subdivision to perform the function involved under a cooperative agreement with the United States Department of Agriculture.

(h) *Accredited veterinarian.* An accredited veterinarian as defined in Part 160 of this chapter.

(i) *State.* Any State, the District of Columbia, Puerto Rico, the Virgin Islands of the United States, or Guam.

(j) *Area.* That portion of any State, the District of Columbia, Puerto Rico, the Virgin Islands of the United States, or Guam which has a separate brucellosis classification under this Part.

(k) *Person.* Any individual, corporation, company, association, firm, partnership, society, or joint stock company or other legal entity.

(l) *Interstate.* From any State into or through any other State.

(m) *Moved.* Shipped, transported, or otherwise moved, or delivered or received for movement.

(n) *Certificate.* An official document issued by a Veterinary Services representative, State representative, or accredited veterinarian at the point of origin of a shipment of domestic animals which shows the official metal eartag, individual animal registered breed association registration tattoo, or individual animal registered breed association registration brand, or registration number or similar individual identification of each animal to be moved, the number of animals covered by the document, the purpose for which the animals are to be moved, the points of origin and destination, the consignor, and the consignee, and which states that the animal or animals identified on the certificate meets the requirements of 9 CFR Part 78 for interstate movement.

(o) *Permit*—(1) *Permit (VS Form 1-27 or comparable state form).* Except for the terms "permit for entry" and "S brand permit," a permit shall mean an official document issued by a Veterinary Services representative, State representative, or accredited veterinarian which is required to accompany "B" branded cattle and bison (or exposed animals moved under official seal). It shall list one of the following: the official metal eartag, individual animal registered breed association tattoo, USDA backtag (when applied serially, only the beginning and the ending numbers need be recorded), registered breed association registration number, or similar individual identification. It shall also list the reactor tag number, owner's name and address, origin and destination locations, number of animals covered, and the purpose of the movement. If a change in destination is desired or becomes necessary, a new permit must be obtained.

(2) *Permit for entry.* A premovement authorization for entry of cattle into a State from the animal health official of the State of destination. It may be oral or written.

(3) *"S" Brand permit.* Any document which is required to accompany animals required to be moved to a quarantined feedlot, or to slaughter, or to an approved stockyard for sale for movement to slaughter. It must show the origin, the destination, the number of restricted cattle, the purpose of the movement, or one of the following: the official metal eartag, individual animal registered breed association tattoo, individual registered breed association registration number, USDA backtag (when applied serially, only the beginning and the ending number need be recorded), or similar individual identification. It shall be prepared at the point of origin. If it is prepared at a quarantined feedlot, it shall be prepared by an accredited veterinarian, a representative of the State animal health official, or an official designated for that purpose by the State animal health official. If it is prepared at any other point of origin, it shall be prepared by an accredited veterinarian, or a representative of the State animal health official. The original shall accompany the animals and shall be delivered to the receiving agent at destination.

(p) *Official test.* (1) *Classification of cattle and bison.*

(i) *Card test.* Card test results are classified as either negative or positive. The card test is to be used as an official test to classify animals as reactors in livestock markets within a State when the State animal health official specifically designates the card test as the official test in livestock markets in his State. Moderate to marked clumping agglutination reaction will be considered a positive reaction.

(ii) *Standard tube test (STT) or standard plate test (SPT).* The blood titers of animals tested by the STT or SPT methods are classified by use of the following:

Official vaccinates				All others			
1:50	1:100	1:200		1:50	1:100	1:200	
–	–	–	NEGATIVE	–	–	–	NEGATIVE
I	–	–	NEGATIVE	I	–	–	SUSPECT
+	–	–	NEGATIVE	+	–	–	SUSPECT
+	I	–	SUSPECT	+	I	–	SUSPECT
+	+	–	SUSPECT	+	+	–	REACTOR
+	+	I	SUSPECT	+	+	I	REACTOR
+	+	+	REACTOR	+	+	+	REACTOR

(iii) *Complement-fixation test (CF).*

(A) Interpretation for all nonvaccinated test-eligible animals:

(*1*) Fifty percent fixation (2 plus) in a dilution of 1:20 or higher—reactor.

(*2*) Fifty percent fixation (2 plus) in a dilution of 1:10 but less than 50 percent fixation (2 plus) in a dilution of 1:20—suspect.

(*3*) Less than 50 percent fixation (2 plus) in a dilution of 1:10—negative.

(B) Interpretation for all test-eligible vaccinated cattle including adult vaccinated animals beginning 2 months postvaccination:

(*1*) Twenty-five percent fixation (1 plus) in a dilution of 1:40 or higher—reactor.

(*2*) Fifty percent fixation (2 plus) in a dilution of 1:10 but less than 25 percent fixation (1 plus) in a dilution of 1:40—suspect.

(*3*) Less than 50 percent fixation (2 plus) in a dilution of 1:10—negative.

(iv) *Rivanol test.* Complete agglutination at dilutions of 1:25 or more is classified as a reactor. Less than complete agglutination at 1:25 is negative. There is no suspect classification with rivanol. Within 5 months postvaccination of adult animals, a less than complete agglutination at the 1:50 dilution is negative.

(v) *Semen plasma test.* The semen plasma test is approved as an official test in bulls used for artificial insemination when used in conjunction with another official serological test. The classification of such animals shall be based on the maximum agglutination titer of either the serological test or the semen test.

(vi) *Buffered acidified plate antigen presumptive test.* Buffered acidified plate antigen tests may be used to classify animals negative on surveillance samples collected at slaughter and at livestock markets.

(vii) *Rapid screening test (RST).* The RST may be used for classifying animals negative in State-Federal laboratories.

(viii) *Milk ring test (also known as Brucellosis Ring Test or BRT).* The milk ring tests conducted on composite milk samples from entire dairy herds are classified as either negative or suspicious (positive). Negative BRT tests classify herds, which are not quarantined as brucellosis affected, as negative for public health ordinances and for surveillance purposes. Herds classified as suspicious require a whole herd blood test to determine the animal and herd status.

(ix) The evaluation of titer responses for all cattle and bison shall be the responsibility of an epidemiologist(s) who has been designated to perform and/or supervise this function in each of the States. He shall take into consideration the animal and herd history and other epidemiologic considerations when making his evaluation. Deviations from the above reactor criteria are acceptable when made by the designated epidemiologist.

(2) *Classification of Swine*—(i) *Card test.* Card test results are classified as either negative or positive. Moderate to marked clumping agglutination reaction is considered positive.

(ii) *Standard tube test.* The blood titers of swine tested by the STT method are classified as follows:

(A) If there are no animals on test with titers greater than Incomplete at, 1:100, if it is not a retest of an infected herd, if it is a complete herd test, or if it is an incomplete test of a validated herd, then use the following: (Animals with a complete titer at 1:100 would be considered reactors.)

1:25	1:50	1:100	
I	–	–	NEGATIVE
+	–	–	NEGATIVE
+	I	–	NEGATIVE
+	+	–	NEGATIVE
+	+	I	NEGATIVE

(B) If there are one or more animals on test with a titer greater than incomplete at 1:100, or if it is a retest of an infected herd, or if it is an incomplete test of a herd of unknown status, then use the following:

1:25	1:50	1:100	
I	–	–	NEGATIVE
+	–	–	REACTOR
+	I	–	REACTOR
+	+	–	REACTOR
+	+	I	REACTOR
+	+	+	REACTOR

(q) *Certified Brucellosis-Free Herd.* A herd of cattle which has qualified for and has been issued a Certified Brucellosis-Free Herd Certificate signed by both the appropriate State animal health official and by the Veterinarian in Charge. A herd may qualify by either of the following methods:

(1) In the case of a dairy herd, by conducting a minimum of three consecutive negative milk ring tests at not less than 90-day intervals, followed by a negative herd blood test conducted within 90 days after the last negative milk ring test; or

(2) By conducting at least wo consecutive negative blood tests of all test-eligible cattle. Tests shall not be less than 10 months nor more than 14 months apart. The status will remain in effect for 12 months beginning with the date of the qualifying herd blood test. A negative blood test of all test-eligible cattle must be conducted within 10 to 12 months of the last certification date for continuous status. Lapsed certification may be reinstated if one herd test is conducted within 14 months of the last certification test date. If a herd is decertified because diseased animals are found, it may be recertified only by repeating the entire certification process.

(r) *Validated Brucellosis-Free Herds of Swine.* Swine herds which are validated as brucellosis free by having one negative herd test of all breeding swine 6 months of age and over in the herd. Revalidation shall be done by a negative test of all breeding swine 6 months of age or over in the herd conducted within 10 to 14 months of the last validation test date or by showing that least 20 percent of the breeding swine in the herd were tested under a market swine testing program (MST) during the year and that at least one-half of the MST sampling occurred during the last 6 months of the validation period, or that all breeding swine 6 months of age or over in the herd are tested in groups according to an approved individual herd plan with each breeding animal tested at least once during the 1-year validation period.

(s) *Validated Brucellosis Free State for Swine.* A State which meets the minimum procedural and qualifying standards and has necessary authorities for classification as a Validated Brucellosis Free Area and which has been certified as such by the appropriate State animal health official, by the Veterinarian in Charge, and by the Deputy Administrator. A State or Area qualifies when it has not diagnosed a case of swine brucellosis in the preceding 12 months and a statistical analysis of combined test results of Market Swine Testing program (MST), change of ownership testing, farm validation tests, and diagnostic tests conducted during the period shows an effect equivalent to either complete herd testing or slaughter surveillance during a one or two year period, as chosen by the State as most appropriate to its marketing needs. Revalidation may be obtained by either herd testing, slaughter surveillance, or combined surveillance, as chosen by the State as most appropriate to its marketing needs.

(t) *Class Free State or Area.* A State or Area which meets standards for classification as a Class Free State or Area and which has been certified as such, on initial classification or on reclassificaiton from a lower class, by the State Animal Health Official, by the Veterinarian in Charge, and by the Deputy Administrator. Reclassification to a lower status can be made by the Deputy Administrator after notice and opportunity to be heard is given to the State. All cattle herds in the State or Area in which brucellosis has been known to exist must be released from quarantine, pursuant to appropriate State law, prior to classification. In addition, if any herds of other species of domestic livestock have been found to be infected with brucellosis or are suspected to be infected with brucellosis, they must be tested negative, slaughtered, or quarantined prior to such designation, so that no known foci of infection in any species is left uncontrolled. The following are the standards to attain the maintain Class Free Status.

(1) *Surveillance*—(i) *Milk ring test (BRT).* The milk ring test of dairy herds shall be conducted at least four times per year at approximately equal intervals on all dairy herds in the State or Area.

(ii) *Market cattle identification program (MCI)*—(A) *Coverage.* All State or Federally inspected slaughtering establishments in the State or Area must participate in the Market Cattle Identification program. The rate of sampling of test-eligible market cattle shall be at least 95 percent at each

State or Federally inspected slaughtering establishment.

(B) *Reactors.* At least 90 percent of all reactors found in the course of market cattle testing (including card test positive animals with or without supporting serologic test results) must be traced to herd of origin and an epidemiologic investigation conducted by State or Veterinary Services representatives within 15 days of their official notification by the cooperative State-Federal laboratory. Herd blood tests when required by the results of the epidemiologic investigation, must be conducted within 30 days of official notification of market cattle test reactors and quarantine issuance or the herds are to continue to be confined to the premises under quarantine.

(iii) *Epidemiologic surveillance*—(A) *Adjacent herds.* All adjacent herds or other herds having contact with cattle in a reactor herd shall be placed under quarantine and have an approved action plan for testing or minitoring the herd(s) in effect within 15 days after notification by State or Veterinary Services representatives of reactors in the herd.

(B) *Epidemiologically traced herds.* All herds from which cattle are sold into an infected herd and all herds which have received cattle from an infested herd shall be placed under quarantine and have an approved action plan or other individual herd plan for testing or monitoring the herd in effect within 15 days of locating the source herd(s) or recipient herd(s).

(2) *Herd infection rate.* (i) The State or Area must remain free from field strain *B. abortus* infection for 12 consecutive months or longer to qualify.

(ii) An epidemiologic investigation of each herd having reactor cattle after designation as a Class Free State or Area shall be conducted within 15 days of finding the reactors to identify the possible sources of infection. All possible sources shall be contacted within 15 days to determine appropriate action. If such investigation is not conducted, the State or Area's classification will be changed to Class A or lower as appropriate.

(3) *MCI reactor prevalence rate.* States or Areas must maintain a 12 consecutive months adjusted MCI reactor prevalence rate not to exceed one reactor per 2,000 cattle tested (0.050 percent). The MCI reactor rate will be adjusted for out-of-State or out-of-Area cattle, recordkeeping errors, and animals traced to either infected herds or herds with negative tests.

(u) *Class A State or Area.* A State or Area which meets standards for classification as a Class A State or Area and which has been certified as such, on initial classification or on reclassification from a lower class, by the State Animal Health official, by the Veterinarian in Charge, and by the Deputy Administrator. Reclassification to a lower class can be made by the Deputy Administrator after notice and opportunity to be heard is given to the State animal health official. The following are the standards to attain and maintain Class A status.

(1) *Surveillance*—(i) *Milk ring test (BRT).* The milk ring test shall be conducted on all dairy herds in the State or Area at least four times per year at approximately equal intervals.

(ii) *Market cattle identification program*—(A) *Coverage.* All State or Federally inspected slaughtering establishments in the State or Area must participate in the Market Cattle Identification program. The rate of sampling of test-eligible market cattle shall be at least 95 percent at each State or Federally inspected slaughtering establishment.

(B) *Reactors.* A minimum of 90 percent of the reactors (including card test positive animals with or without supporting serologic test results) must be traced to the herd of origin and an epidemiologic investigation conducted by State or Veterinary Services within 15 days of their official notification by the cooperative State-Federal laboratory. Herd blood tests, when required by the results of the epidemiologic investigation, must be conducted within 30 days of official notification by State or Veterinary Services of market cattle test reactors or the herds are to be confined to the premises under quarantine.

(iii) *Epidemiologic surveillance*—(A) *Adjacent herds.* All adjacent herds or herds having contact of cattle with the reactor herd shall have an approved action plan for testing or monitoring the herd in effect within 15 days of notification of infection in the reactor herd.

(B) *Epidemiologically traced herds.* All herds from which cattle are sold into an infected herd and all herds which have received cattle from an infected herd shall have an approved action plan for testing or monitoring the herd in effect within 15 days of locating the source herd(s) or recipient herd(s).

(2) *Herd infection rate.* (i) States or Areas must not exceed a herd infection rate, based on the number of reactors found within the State or Area during any 12 consecutive months, due to field strain *B. abortus* of 0.25 percent or 2.5 herds per 1,000, except in states with 10,000 or fewer herds. A special review by the Deputy Administrator will be made to determine if such small herd population States would qualify for Class A status. Locations of herds, sources of current infections, and control measures taken by the State will be considered.

(ii) An epidemiologic investigation of each herd with reactor cattle shall be conducted to identify the possible sources of infection by State or Veterinary Services representatives within 15 days of being notified that reactor cattle have been found by the cooperative State-Federal laboratory. All such possible sources shall be contacted within an additional 15 days to determine appropriate action.

(3) *MCI reactor prevalence rate.* The State or Area must maintain a 12 consecutive months adjusted MCI reactor prevalence rate not to exceed one reactor per 1,000 cattle tested (0.10 percent). The MCI reactor prevalence rate will be adjusted for out-of-State and out-of-Area cattle, recordkeeping errors, and animals traced to either infected herds or herds with negative tests.

(v) *Class B State or Area.* A State or Area which meets standards for classification as a Class B State or Area and which has been certified as such, on initial classification or on reclassification from a lower class, by the State Animal Health Official, by the Veterinarian in Charge, and by the Deputy Administrator. Reclassification to a lower class can be made by the Deputy Administrator after notice and opportunity to be heard is given to the State. The following are the standards to attain and maintain Class B status.

(1) *Surveillance*— (i) *Milk ring test (BRT).* The milk ring test shall be conducted on all dairy herds in the State or Area at least four times per year at approximately equal intervals.

(ii) *Market cattle identification program*—(A) *Coverage.* All State or Federally inspected slaughtering establishments in the State or Area must participate in the Market Cattle Identification program. The rate of sampling of test-eligible market cattle shall be at least 95 percent at each State or Federally inspected slaughtering establishment.

(B) *Reactors.* A minimum of 80 percent of the reactors (including card test positive animals (with or without supporting serologic test results)) must be traced to the herd of origin and an epidemiologic investigation conducted by State or Veterinary Services representatives within 30 days of their being officially notified by the cooperative State-Federal laboratory of the finding of reactor cattle. Herd blood tests, when required by the results of the epidemiologic investigation, must be conducted within 30 days of such official notification of market cattle test reactors or the herds are to be confined to the premises under quarantine.

(iii) *Epidemiologic surveillance*—(A) *Adjacent herds.* All adjacent herds or herds having contact of cattle with the reactor herd shall have an approved action plan for testing or monitoring the herd in effect within 45 days of notification of infection in the reactor herd.

(B) *Epidemiologically traced herds.* All herds from which cattle are sold into an infected herd and all herds which have received cattle from an infected herd shall have an approved action plan for testing or monitoring the herd in effect within 45 days of locating the source herd(s) or recipient herd(s).

(2) *Herd infection rate.* (i) States or Areas must not exceed an accumulated 12 consecutive months herd infection

rate, based on the number of reactors found within the State/Area during that period, due to field strain *B. abortus* of 1.5 percent or 15 herds per 1,000 except in states with 1,000 or fewer herds. A special review by the Deputy Administrator will be made to determine if such small herd population States qualify for Class B status. Locations of herds, sources of current infections, and control measures taken by the State will be considered.

(ii) An epidemiologic investigation of each herd with reactor cattle in it shall be conducted by State or Veterinary Services representatives within 45 days of their notification by the cooperative State-Federal laboratory of the finding of reactor cattle to identify the possible sources of infection. All such possible sources shall be contacted within an additional 30 days to determine appropriate action, to maintain Class B status.

(3) *MCI Reactor prevalence rate.* The State or Area must maintain a 12 consecutive months adjusted MCI reactor prevalence rate not to exceed three reactors per 1,000 cattle tested (0.30 percent). The MCI reactor prevalence rate will be adjusted for out-of-State and out-of-Area cattle, recordkeeping errors, and animals traced to either infected herds or herds with negative tests.

(w) *Class C State or Area.* A State or Area which meets standards for classification as a Class C State or Area and which has been certified as such, on initial classification or on reclassification from being quarantined, by the State Animal Health Official, by the Veterinarian in Charge, and by the Deputy Administrator. Reduction in status to "quarantined" can be made by the Deputy Administrator after notice and opportunity to be heard is given to the State. The following are the standards to attain and maintain Class C status.

(1) *Surveillance*—(i) *Milk ring test (BRT).* The milk ring test shall be conducted on all dairy herds in the State or Area at least four times per year at approximately equal intervals.

(ii) *Market cattle identification program*—(A) *Coverage.* All State or Federally inspected slaughtering establishments in the State or Area must participate in the Market Cattle Identification program. The rate of sampling of test-eligible market cattle shall be at least 95 percent at each State or Federally inspected slaughtering establishment.

(B) *Reactors.* A minimum of 80 percent of the reactors (including card test positive animals with or without supporting serologic test results) must be traced to the herd of origin and an epidemiologic investigation conducted by State or Veterinary Services representatives within 30 days of their official notification by the cooperative State-Federal laboratory that reactors have been found. Herd blood tests, when required by the results of the epidemiologic investigation, must be conducted within 30 days of such official notification of market cattle test reactors or the herds are to be confined to the premises under quarantine.

(iii) *Epidemiologic surveillance*—(A) *Adjacent herds.* All adjacent herds or herds having contact of cattle with the reactor herd shall have an approved action plan for testing or monitoring the herd in effect within 45 days of notification of infection in the reactor herd.

(B) *Epidemiologically traced herds.* All herds from which cattle are sold into an infected herd and all herds which have received cattle from an infected herd shall have an approved action plan for testing or monitoring the herd in effect within 45 days of locating the source herd(s) or recipient herd(s).

(2) *Herd infection rate.* (i) A State or Area with 1,000 or more herds having an accumulated 12 consecutive months herd infection rate, based on the number of reactors found within the State/Area during that period, due to field Strain *B. abortus* exceeding 1.5 percent or 16 herds or more per 1,000 is a Class C State or Area. A special review will be conducted by the Deputy Administrator in a State with a smaller herd population but with a herd infection rate exceeding 1.5 percent to determine if it should be included as a Class C State. Locations of herds, sources of current infections, and control measures taken by the State will be considered.

(ii) An epidemiologic investigation of each herd with reactor cattle shall be conducted by State o. Veterinary Services representatives within 45 days of their notification by the Cooperative State-Federal laboratory of the finding of reactor cattle to identify the possible sources of infection. All such possible sources shall be contacted to determine appropriate action within an additional 30 days.

(3) *MCI reactor prevalence rate.* The State or Area 12 consecutive months adjusted MCI reactor prevalence rate exceeds three reactors per 1,000 cattle tested (0.30 percent). The MCI reactor prevalence rate will be adjusted for out-of-State and out-of-Area cattle, recordkeeping errors, and animals traced to either infected herds or herds with negative tests.

(4) *Compliance with minimum procedural standards.* (i) A State must implement and maintain minimum procedural standards.

(ii) A State or Area must make continued progress as judged over a two year period in reducing the prevalence of brucellosis as determined by epidemiologic evaluation or it will be placed under federal quarantine.

(x) *Brucellosis reactor*—(1) *Cattle and bison.* (i) Official vaccinates of dairy breeds 20 months of age and over and official vaccinates of bison or beef breeds 24 months of age and over (as evidenced by the presence of the first pair of permanent incisor teeth) or official vaccinates under these ages that are parturient (springers) or postparturient are classified serologically as reactors when they disclose complete standard plate test (SPT) or standard tube test (STT) agglutination reactions in the blood titer dilution of 1:200 or higher, are positive to the brucellosis card test where it has been the only test conducted, disclose titers of 25 percent fixation (1 plus) in a dilution of 1:40 or higher on the complement-fixation (CF) test, disclose a complete agglutination reaction in the 1:25 dilution or higher on the rivanol test, or are found infected by other diagnostic procedures such as isolation of *Brucella abortus.*

(ii) All other bison and cattle more than 6 months of age are classified serologically as reactors when they disclose a complete agglutination reaction in the blood titer dilution of 1:100 or higher, are positive to the card test where it has been the only test conducted, disclose titers of 50 percent fixation (2 plus) in a dilution of 1:20 or higher on the complement-fixation test, disclose a complete agglutination reaction in the 1:25 dilution or higher on the rivanol test, or are found infected by other diagnostic procedures such as isolation of *Brucella abortus.*

(iii) Where approved whole herd vaccination of herds at high risk (including Certified Brucellosis-Free Herds, infected herds, or herds not Certified Brucellosis-Free) with reduced doses of *B. abortus* Strain 19 has been carried out, adult vaccinated (AV), tattooed or branded animals are considered reactors if the CF test has at least 25 percent fixation (1 plus) in a dilution of 1:40 or higher. A first test is recommended at 2 months or as early thereafter as possible following the whole herd vaccination in order to facilitate elimination of field strain infection. At less than 5 months postvaccination, animals are considered reactors if a complete agglutination reaction occurs in the 1:50 dilution or higher on the rivanol test. On such tests at more than 5 months postvaccination, animals are considered reactors if a complete agglutination reaction occurs in the 1:25 dilution or higher on the rivanol test.

(iv) The evaluation of titer responses for all cattle and bison shall be the responsibility of an epidemiologist(s) who has been designated to perform and/or supervise this function in each of the States. He shall take into consideration the animal and herd history and other epidemiologic considerations when making his determination. Deviations from the above reactor criteria are acceptable when made by the designated epidemiologist.

(2) *Swine.* Any swine that disclose complete STT agglutination reactions to the blood titer dilution of 1:100 or higher. Any swine in an infected herd or those on an incomplete test of a herd of unknown status having a complete reaction in the 1:25 dilution or higher. Any swine disclosing a positive card test reaction or found infected by another official test or by isolating or

otherwise identifying the brucella organism.

(y) *Brucellosis suspect*—(1) *Cattle and bison.* (i) Official vaccinates of dairy breeds 20 months of age or over and official vaccinates of bison or beef breeds 24 months of age and over (as evidenced by the presence of the first pair of permanent incisor teeth) or official vaccinates under these ages that are parturient (springers) or postparturient are classified as suspects when they disclose SPT or STT agglutination reactions in the dilution of 1:100 or any partial agglutination in the 1:200 dilution. Cattle or bison negative to the SPT or STT tests but which are positive to the brucellosis card test, if it is performed, are classified as suspects. When the CF test is conducted, all test-eligible cattle having less than 25 percent fixation (1 plus) in a dilution of 1:40 and 50 percent (2 plus) or more in a dilution of 1:10 are classified as suspects.

(ii) All other cattle and bison more than 6 months of age are classified as suspects when they disclose any SPT or STT agglutination reactions in the blood titer dilution of 1:50 or incomplete agglutination in the 1:100 dilution. Cattle or bison negative to the SPT or STT tests, but which are positive to the brucellosis card test, if it is performed, are classified as suspects. When the CF test is conducted, all cattle or bison more than 6 months of age having less than 50 percent fixation (2 plus) in a dilution of 1:20 and 50 percent fixation (2 plus) or more in a dilution of 1:10 are classified as suspects.

(iii) The evaluation of titer responses for all cattle and bison shall be the responsibility of an epidemiologist(s) who has been designated to perform and/or supervise this function in each of the States. He shall take into consideration the animal and herd history and other epidemiologic considerations when making his determination. Deviations from the above suspect criteria are acceptable when made by the designated epidemiologist.

(2) *Swine.* Card test positive swine disclosed in a herd which is otherwise negative to serological or bacteriological tests and as judged by epidemiological evidence, will be held under whole herd quarantine until subjected to additional official brucellosis tests to determine the status of the animals, that is, whether they are actually negative or reactors.

(z) *Brucellosis negative*—(1) *Cattle and bison.* (i) Official vaccinates of dairy breeds 20 months of age or over and official vaccinates of bison and beef breeds 24 months of age and over (as evidenced by the presence of the first pair of permanent incisor teeth) or official vaccinates under these ages that are parturient (springers) or postparturient are classified as negative when the SPT or STT disclose reactions of not more than complete agglutination in the 1:50 dilution, are negative to the brucellosis card test, disclose 25 percent fixation or less (1 plus) at the 1:10 dilution of the CF test, or disclose less than complete agglutination at the 1:25 dilution on the rivanol plate agglutination test. If only one test is run, that test must be negative; if more than one test is run, all reactions must be negative for the animal to be classified as brucellosis negative.

(ii) All other such cattle and bison more than 6 months of age are classified as negative serologically when the SPT or STT discose reactions of not more than complete agglutination in the 1:25 dilution, are negative to the brucellosis card test, disclose 25 percent fixation or less (1 plus) at the 1:10 dilution on the CF test, or disclose less than complete agglutination at the 1:25 dilution on the rivanol plate agglutination test.

(iii) Blood samples collected at slaughter are negative when no evidence of agglutination is disclosed by the rapid screening test (RST) or buffered acidified plate antigen test. Blood samples collected at livestock markets are negative when no evidence of agglutination is disclosed on the buffered acidified plate antigen test. Blood samples collected at slaughter or at livestock markets showing some agglutination to the rapid screening test or the buffered acidified plate test, as appropriate, are classified negative if the confirmatory test (brucellosis card test or SPT) is negative.

(iv) The evaluation of titer responses for all cattle and bison shall be the responsibility of an epidemiologist(s) who has been designated to perform and/or supervise this function in each of the States. He shall take into consideration the animal and herd history and other epidemiologic considerations when making his determination. Deviations from the above negative criteria are acceptable when made by the designaged epidemiologist.

(2) *Swine.* (i) Any swine from an infected herd or herd of unknown status that discloses a STT agglutination reaction of less than complete agglutination in the blood titer dilution 1:25 or that has no reaction to the card test is classified as negative.

(ii) Any swine from a Validated Brucellosis-Free herd not known to be infected in a validated brucellosis free area, or any swine on a complete herd test that discloses a STT agglutination reaction of less than complete agglutination in the blood titer dilution of 1:100 or that has no reaction to the card test.

(aa) *Brucellosis exposed animal.* Except for brucellosis reactors, animals that are part of a known infected herd, or are in a quarantined feedlot or a quarantined pasture, or are brucellosis suspects, or that have been in contact with brucellosis reactors in marketing channels for a period of 24 hours or for a period of less than 24 hours if the reactor has aborted, calved or farrowed within the past 30 days or has a vaginal or uterine discharge, are considered to be exposed regardless of the bloc ' tests results.

(bb) *Herd.* A herd is:

(1) all animals under common ownership or supervision that are grouped on one or more parts of any single premises (lot, farm, or ranch) and

(2) all animals under common ownership on two or more premises which are geographically separated, but on which the animals have been interchanged or where there has been contact among the animals on the different premises.

(cc) *Animals.* Cattle, bison, and breeding swine.

(dd) *Farm of origin of cattle and bison.* A farm or other premises where the cattle or bison to be shipped interstate were born or have been kept for not less than 4 months prior to the date of shipment and which premises, within the 4 months prior to the date of shipment, have not been used to assemble cattle or bison from any other premises.

(ee) *Herd of origin of swine.* Any herd in which swine are farrowed and raised or in which such swine were maintained for a period of 30 days immediately prior to shipment interstate.

(ff) *Breeding swine.* Any swine 6 months of age or over which are maintained for breeding purposes as a part of a formal breeding program.

(gg) *Sow.* A female swine which has given birth to one or more litters of pigs or which is parturient.

(hh) *Boar.* An uncastrated male swine which has reached a stage of maturity rendering him capable of being used as a breeding animal including those which through age or infirmity are no longer capable of such use.

(ii) *Recognized slaughtering establishment.* Any slaughtering establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or a State Meat Inspection act.

(jj) *Specifically approved stockyard.* A stockyard specifically approved for the purposes of the regulations in this part in accordance with § 78.25(b).

(kk) *Herd blood test*—(1) *Cattle or bison.* The herd blood test shall include all test-eligible cattle or bison.

(2) *Swine.* The herd test shall include all breeding swine 6 months of age and older. All swine being held for feeding purposes, separate and apart and without physical contact with breeding swine, are exempt from herd test requirements.

(ll) *Test-eligible cattle and bison*—(1) *Herd blood test.* Test-eligible animals shall include all cattle or bison over 6 months of age, except steers, spayed heifers, official calfhood vaccinates of the dairy breeds under 20 months of age, the official calfhood vaccinates of bison or beef breeds under 24 months of age (as evidenced by the presence of the first pair of permanent incisor teeth) which are not parturient (springers) or postparturient.

(2) *Market cattle identification (MCI) blood testing*—(i) *Blood sampling at slaughtering establishment.* All cows and bulls over 2 years of age are test-eligible.

(ii) *Blood testing at livestock markets or farms or ranches.* All cattle over 18 months of age (as evidenced by the loss of the first pair of temporary incisor teeth) except steers, spayed heifers, official calfhood vaccinates of the dairy breeds under 20 months of age, and official calfhood vaccinates of beef breeds under 24 months of age (as evidenced by the presence of the first pair of permanent incisor teeth) which are not parturient (springers) or post-parturient.

(3) *Test for other movements.* Same as § 78.1(ll)(2)(ii).

(mm) *Quarantined area.* Any area listed in § 78.22.

(nn) *Qualified herd.* (1) Any herd of cattle or bison in a quarantined area which is not known to be affected with brucellosis and which has been subjected to two consecutive official tests for brucellosis and found negative. The first of these two official tests of the herd shall be conducted not more than 240 days nor less than 120 days prior to the date of classification as a qualified herd. The second official test may not be conducted less than 90 days nor more than 150 days after the first test. Additionally, the second test must be within 120 days of the date of classification as a qualified herd. Certified brucellosis-free herds may qualify for classification as qualified herds by having a negative herd blood test 120 days prior to or after the establishment of a quarantine. (2) In order to remain a qualified herd, a herd must be subjected to successive requalifying official tests and found negative on each test. Each such requalifying test shall be conducted not more than 120 days from the date of the preceding official test. All cattle or bison added to a qualified herd must have been included in the preceding two official tests to qualify as cattle or bison from the qualified herd.

(oo) *Quarantined feedlot.* A quarantined feedlot shall be a confined area under official State quarantine and shall be approved jointly by the State animal health official and the Veterinarian in Charge. Approval will be granted only after inspection and after the feedlot demonstrates that all animals are secure and isolated from contact with any other nonquarantined feedlot or pasture animals, that there are facilities for identifying animals as required, and that there is no possibility of disease being mechanically transmitted from the premises. All cattle and bison, except steers and spayed heifers in a quarantined feedlot shall be classified as exposed to brucellosis. The quarantined feedlot shall be maintained for feeding of cattle and bison for slaughter, with no provisions for pasturing or grazing. All cattle and bison, except steers and spayed heifers, leaving such feedlot must move directly to slaughter accompanied by a permit, directly to another quarantined feedlot accompanied by a permit from the State animal health official, or, after being "S" branded at the feedlot, directly to a specifically approved stockyard to be sold for movement to slaughter or to another quarantined feedlot accompanied by a permit. However, finished fed cattle moving directly to recognized slaughtering establishments are exempt from the requirement for identification and the requirement to be accompanied by a permit. The animal health officials shall establish procedures for accounting for all animals entering or leaving such quarantined feedlots.

(pp) *Quarantined pasture.* A quarantined pasture shall be a designated, confined grazing area under official State quarantine and shall be approved jointly by the State animal health official and the Veterinarian in Charge. Approval will be granted only after inspection and after the owners of the pasture demonstate that all animals are secure and isolated from contact with any other nonquarantined feedlot or pasture animals, that there are facilities for identifying the animals as required and that there is no possibility of disease being mechanically transmitted from the premises. The quarantined pasture shall be for the purpose of utilizing available forage to grow or to improve flesh condition of cattle. No cattle may be moved interstate into these quarantined pastures, but they shall be restricted in use for cattle originating within the State. In all areas, these animal health officials shall request approval from the Deputy Administrator, Veterinary Services, APHIS, and justify the need. An intensified brucellosis eradication effort, which produces large numbers of exposed or adult vaccinated animals needing the grazing period to reach slaughter condition would be an acceptable justification. All animals, except steers and spayed heifers, in a quarantined pasture shall be classified as exposed to brucellosis. All cattle shall be of the same sex (e.g., all cows or all bulls), except that neutered animals may share the quarantined pasture. All animals except steers and spayed heifers must be permanently identified with a hot iron "S" brand either on the left jaw or high on the tailhead (over the fourth to the seventh coccygeal vertebrae) upon entering the quarantined pasture. All animals except steers and spayed heifers leaving the quarantined pasture must move to immediate slaughter at a recognized slaughtering establishment or to a quarantined feedlot. The movement shall be in accordance with established procedures for handling exposed animals, including issuance of "S" brand permits prior to movement. The State animal health official and Veterinarian in Charge shall establish procedures for accounting for all animals entering or leaving the quarantined pasture. Any procedures which allow the number of animals on the premises at any time to be accurately determined would be acceptable. All exposed cattle must vacate the premises on or before the expiration of approval, which may not last longer than 10 months.

(qq) *"S" branded cattle or bison.* Cattle or bison which have been identified by branding with a hot iron the letter "S" at least 5cm x 5cm (2 x 2 inches) in size on the left jaw or high on the tailhead (over the fourth to the seventh coccygeal vertebrae).

(rr) *Official metal eartag.* A Veterinary Services approved metal identification eartag conforming to the nine-character alpha-numeric National Uniform Eartagging System. It provides unique identification for each individual animal.

(ss) *Market cattle identification (MCI) test animals.* Market cattle identification test animals are test-eligible animals moving through auction markets, stockyards, or to slaughtering establishments. Also, they are those animals assembled at farms or ranches that are being readied for movement to markets, stockyards, slaughtering establishments or other places for sale, such as consignment or dispersal sales. Such animals shall be identified by eartag and/or backtag to the herd of origin prior to or at the first market, stockyard or slaughtering establishment they reach in marketing channels.

(tt) *Approved brucella vaccine.* A *Brucella abortus* Strain 19 product that is approved by and produced under license of the U.S. Department of Agriculture for injection into cattle and bison to enhance their resistance to brucellosis.

(uu) *Whole herd vaccination.* The vaccination of all female animals in a herd over 2 months of age, including animals older than the age for official calfhood vaccination, which may be vaccinated when their entire herd is authorized, by the State animal health official and by the Veterinarian in Charge, to be vaccinated with a reduced dose of vaccine.

(vv) *Official-vaccinate.* (1) In States administering a standard dose approved brucella vaccine containing a minimum of 25 billion live cells per 5 ml dose for calfhood vaccination:[1]

(i) *Official calfhood vaccinate.* Female cattle of a dairy breed vaccinated by a Veterinary Services representative, State representative, or accredited veterinarian with a standard dose approved *Brucella abortus* Strain 19 vaccine in accordance with its labeling while from 2 through 6 months (60 to 179 days) of age. Female cattle of a beef breed or female bison vaccinated by a Veterinary Services representative, State representative, or accredited veterinarian with a standard dose approved *Brucella abortus* Strain 19 vaccine in accordance with its labeling while from 2 through 10 months (60 to 299 days) of age: *Provided, however,* That female cattle or bison vaccinated prior to January 1, 1982, in accordance with the definition of an official vaccinate as incorporated by reference into this part at the date of said vaccination, shall be deemed to be an official vaccinate.

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[1] A listing of these States may be obtained from Veterinary Services, Federal Building, Room 814, Hyattsville, MD 20782.

(ii) *Official adult vaccinate.* Female cattle of a dairy breed vaccinated by a Veterinary Services representative, State representative, or accredited veterinarian with an approved reduced dose *Brucella abortus* Strain 19 vaccine, diluted so as to contain at least 300 million and not more than 3 billion live cells per 2 ml dose, while over 6 months (179 days) of age and as part of a whole herd vaccination plan authorized jointly by the State animal health official and Veterinarian in Charge. Female cattle of a beef breed or female bison vaccinated by a Veterinary Services representative, State representative, or accredited veterinarian with an approved reduced dose *Brucella abortus* Strain 19 vaccine, diluted so as to contain at least 300 million and not more than 3 billion live cells per 2 ml dose, while over 10 months (299 days) of age and as part of a whole herd vaccination plan authorized jointly by the State animal health official and the Veterinarian in Charge: *Provided, however,* That female cattle or bison vaccinated prior to January 1, 1982, in accordance with the definition of an official adult vaccinate as incorporated by reference into this part at the date of said vaccination, shall be deemed to be an official adult vaccinate.

(2) In States administering the reduced dose approved brucella vaccine containing at least 300 million and not more than 3 billion live cells per 2 ml dose for calfhood vaccination:[1]

(i) *Official calfhood vaccinate.* Female cattle of any breed or female bison vaccinated while from 4 through 12 months (120 through 365 days) of age by a Veterinary Services representative, State representative, or accredited veterinarian with a reduced dose *Brucella abortus* Strain 19 vaccine, diluted so as to contain at least 300 million and not more than 3 billion live cells per 2 ml dose: *Provided, however,* That female cattle or bison vaccinated prior to January 1, 1982, in accordance with the definition of an official vaccinate as incorporated by reference into this part at the date of said vaccination, shall be deemed to be an official vaccinate.

(ii) *Official adult vaccinate.* Female cattle of any breed or female bison vaccinated when more than one-year (365 days) of age by a Veterinary Services representative, State representative, or accredited veterinarian with a reduced dose *Brucella abortus* Strain 19 vaccine, diluted so as to contain at least 300 million and not more than 3 billion live cells per 2 ml dose, as a part of whole herd vaccination plan authorized jointly by the State animal health official and the Veterinarian in Charge: *Provided, however,* That a female cattle or bison vaccinated prior to January 1, 1982, in accordance with the definition of an official adult vaccinate as incorporated by reference into this part at the date of said vaccination, shall be deemed to be an official adult vaccinate.

(ww) *Identification of vaccinates*—(1) *Calfhood vaccinates.* Calfhood vaccinated animals shall be permanently identified as vaccinates by tattoo and by official vaccination eartags. However, if already identified with an official metal eartag prior to vaccination, an additional tag is not required. Vaccination tattoos must be applied to the right ear. The tattoo must include the U.S. Registered Shield and "V", which will be preceded by a number indicating the quarter of the year and will be followed by a number corresponding to the last digit of the year in which the vaccination was done. Official vaccination eartags shall be applied to the right ear. The eartag must include the State numerical prefix as assigned by the National Uniform Eartagging System and a "V", followed by two letters and four numbers which will uniquely individually identify such vaccinated animal. Individual animal registered breed association registration tattoos or individual animal registered breed association registration brands may be substituted for official metal eartags.

(2) *Adult vaccinates.* Animals which have been vaccinated over calfhood

age in authorized "whole herd" vaccination herds shall be permanently identified as vaccinates by the following procedures:

(i) *Brucellosis affected herds and herds not Certified Brucellosis-Free but at high risk.* Animals will be identified by a "V" hot brand on the right jaw, or by an official AV (adult vaccination) tattoo in the right ear preceded by the quarter of the year and followed by the last digit of the year, as well as official metal eartag (or individual animal registered breed association registration tattoo or individual animal registered breed association registration brand).

(ii) *Certified Brucellosis-Free herds.* Animals will be identified by a "V" hot branded on the right jaw, or by an official AV (adult vaccination) tattoo in the right ear preceded by the quarter of the year and followed by the last digit of the year as well as the official metal eartag (or individual animal registered breed association registration tattoo or individual animal registered breed association registration brand).

(xx) *Approved action plan or approved individual herd plan.* (1) A herd management and testing plan which is designed by the herd owner, his veterinarian if so requested, and a veterinarian of the Cooperative Brucellosis Eradication Program to control and eventually eradicate brucellosis from an affected herd. Plans must be approved jointly by the State animal health official and the Veterinarian in Charge. A similar plan for determining the true status of suspects and preventing exposure to brucellosis within the herd is also within the meaning of the term "Individual Herd Plan" or "Approved Action Plan."

(2) The plan must call for the most appropriate veterinary procedures and proven herd management procedures to control the spread of brucellosis within the herd and thereby eradicate the disease from the herd.

(yy) *Official seal.* A serially numbered, metal or plastic strip, consisting of a self-locking device on one end and a slot on the other end, which forms a loop when the ends are engaged, which cannot be reused if opened, and which is applied by a representative of the Veterinarian in Charge or the State animal health official.

(zz) *Finished fed cattle.* Cattle in a quarantined feedlot which have been fattened on a ration of feed concentrates to reach a slaughter condition equivalent to the slaughter condition which would be attained on full feed on a high concentrate grain ration for 90 days.

(aaa) *Herd known to be affected.* Any herds in which any animal has been classified as a brucellosis reactor, and which has not been released from quarantine.

(bbb) *Herd not known to be affected.* Any herd in which no animal has been classified as a brucellosis reactor, also any herd in which any animal has been classified as a brucellosis reactor and which has been released from quarantine.

(ccc) *Parturient.* Visibly prepared to give birth or within 2 weeks of giving birth.

(ddd) *Post parturient.* Having already given birth.

(eee) *Untested test-eligible cattle.* Those cattle which are of test-eligible age and which are required to be tested by § 78.9 of this Part for interstate movement, but which have not been tested in compliance with the specific requirements applicable to cattle originating at that location.

(fff) *Epidemiology.* A branch of medical science that deals with the incidence, distribution, and control of disease in the animal population.

(ggg) *Epidemiologist.* A Doctor of Veterinary Medicine who has received a Master's degree in Epidemiology or one who has completed a course of study in epidemiology sponsored by the Animal and Plant Health Inspection Service, Veterinary Services, United States Department of Agriculture.

(hhh) *Originates.* Having been moved to the premises or herd indicated from a State/Area of equal or higher class, or have been born in the herd indicated, or having been moved to the premises or herd indicated from a State/Area of lower status and kept on the premises or in the herd indicated for not less than 4 months prior to the movement in question.

(iii) *Moved (movement) in interstate commerce.* Moved from the point of origin of the interstate movement to the animals' final destination, such as a slaughtering establishment or a farm for breeding or raising, and including any temporary stops for any purpose prior to movement to final destination, such as stops at a stockyard or dealer premises for feed, water, rest, or sale.

[47 FR 55644, Dec. 13, 1982, as amended at 50 FR 11500, Mar. 22, 1985; 50 FR 45987, Nov. 6, 1985]

§ 78.2 Notice relating to existence of brucellosis.

Notice is hereby given that the contagion of brucellosis may exist in domestic animals in each State.

§ 78.3 Handling of certificates or permits for movement of animals.

(a) Whenever the regulations in this part require a certificate or a permit for movement of animals and the animals are moved by a transportation agency issuing waybills or other forms of billing covering the movement, the certificate, or permit, for movement shall be delivered to such transportation agency by the shipper or his agent at the time the animals are delivered for shipment; shall become the property of the transportation agency; shall be attached to the billing by the transportation agency; shall accompany such billing to the destination of the animals; and should be filed with such billing for future reference.

(b) Whenever the regulations in this part require a certificate or a permit for movement of animals and the animals are moved by a transportation agency not issuing waybills or other forms of billing, or moved by any other means, the certificate or permit for movement shall accompany the animals to their destination and be delivered to the consignee, or, in case the consignor and the consignee are the same person, to the first person purchasing the animals during or after such movement, or to the person to whom the animals are delivered.

(c) The Veterinarian Services representative, State representatives, or accredited veterinarian issuing a certificate or permit required for the interstate movement of cattle under the regulations in this part, except for "permits for entry" and "'S' brand permits" required by § 78.1(o)(2), and (3), shall forward a copy thereof to the proper livestock sanitary official of the State of destination of the animals.

[40 FR 17816, Apr. 22, 1975, as amended at 47 FR 55652, Dec. 13, 1982]

§ 78.4 Handling in transit of cattle and bison moved interstate.

Cattle and bison moving interstate, except cattle and bison consigned to immediate slaughter or to a quarantined feedlot,[2] shall be moved only in a means of conveyance which has been cleaned in accordance with the provisions of §§ 71.5, 71.7, 71.10, and 71.11 of this subchapter, and if unloaded in the course of such movement, shall be handled only in pens at specifically approved stockyards cleaned in accordance with the provisions of §§ 71.4, 71.7, 71.10, and 71.11 of this subchapter or in pens at feed, water, and rest stations cleaned in accordance with the provisions of §§ 71.4, 71.7, 71.10, and 71.11 of this subchapter.

Subpart B—Restrictions on Interstate Movement of Cattle Because of Brucellosis

§ 78.5 General restrictions.

Cattle may not be moved interstate except in compliance with the regulations in this subpart.

§ 78.6 Steers and spayed heifers.

Steers and spayed heifers of any age may be moved interstate from any area without restrictions under this subpart.

[47 FR 55652, Dec. 13, 1982]

§ 78.7 Brucellosis reactor cattle.

Brucellosis reactor cattle may only be moved interstate for immediate slaughter directly to a recognized slaughtering establishment or from a farm of origin directly to no more than one specifically approved stockyard and then directly to such a recognized slaughtering establishment and only in accordance with the following requirements:

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[2] A list of quarantined feedlots in any State may be obtained from the State Representative.

(a) *Marking of brucellosis reactor cattle.* Brucellosis reactor cattle shall be marked for identification by branding the letter "B" on the left jaw in letters not less than 2 nor more than 3 inches high, and attaching to the left ear a metal tag bearing a serial number and the inscription "U.S. Reactor" or a similar State reactor tag.

(b) *Required permit.* Brucellosis reactor cattle shall be accompanied to destination by a permit for movement of the animals in accordance with § 78.3.

(c) *Marking of records.* Each transportation agency moving brucellosis reactor cattle in the course of their interstate movement shall plainly write or stamp upon the face of each waybill, conductor's manifest, switch order, vehicle interchange record, or other document, which it prepares in connection with such movement, the words "Brucellosis Reactor."

(d) *Segregation of brucellosis reactor cattle en route interstate.* Brucellosis reactor cattle shall not be moved interstate in a railroad car, boat, truck, or other means of conveyance, containing nonreactor animals susceptible to brucellosis, unless all of the animals are for immediate slaughter, or unless reactor cattle are kept separate from the other animals by a partition securely affixed to the sides of the means of conveyance.

[40 FR 17816, Apr. 22, 1975, as amended at 44 FR 55806, Sept. 28, 1979]

§ 78.8 Brucellosis-exposed cattle.

Except as provided in Part 51 of the regulations, brucellosis-exposed cattle may be moved interstate only as follows:

(a) *Movement of brucellosis-exposed cattle for immediate slaughter.* Finished fed cattle from quarantined feedlots move directly to recognized slaughtering establishments without further restrictions under this Part. Other brucellosis-exposed cattle may be moved directly to a recognized slaughtering establishment, or from a farm of origin directly through no more than one specifically approved stockyard and then directly to a recognized slaughtering establishment, only if such cattle are:

(1) Individually identified by a Veterinary Services approved metal eartag or a USDA backtag;

(2) Accompanied by a VS Form 1-27 permit or "S" brand permit; and

(3) Such cattle are:

(i) "S" branded before the animals leave the premises from which they move interstate, or

(ii) In the instances when a claim for indemnity is being made by the owner under the provisions of 9 CFR 51.3, they are identified with the letter "B" as prescribed in 9 CFR 51.5, or

(iii) If they are official adult vaccinates, they have been hot-iron branded "AV" or "V" on the right jaw, or

(iv) Moved in vehicles closed with official seals. Official seals shall only be applied or removed by a Veterinary Services representative, State representative, accredited veterinarian or by other persons authorized for this purpose by a Veterinary Services representative. If the movement is directly to a specifically approved stockyard and then to a recognized slaughtering establishment, a separate permit shall be required for the movement of such cattle from such stockyard directly to such slaughtering establishment if that movement is interstate. The official seal number(s) shall be recorded on the permit.

(v) If they are moving directly from a quarantined feedlot to a recognized slaughtering establishment, non "S" branded cattle will not be required to be "S" branded prior to movement.

(b) *Movement of brucellosis-exposed cattle to quarantined feedlots.* Such cattle may only be moved directly to a quarantined feedlot or from a farm of origin directly through no more than one specifically approved stockyard and then directly to a quarantined feedlot, and then only if such cattle are:

(1) Individually identified by a Veterinary Services approved metal eartag or an USDA backtag;

(2) Accompanied by a VS Form 1-27 permit or "S" brand permit; and

(3) Such cattle are:

(i) "S" branded before they leave the premises from which they move interstate, or

(ii) Officially adult vaccinated cattle and have been hot-iron branded "AV" or "V" on the right jaw.

If the movement is directly to a specifically approved stockyard for sale and shipment to a quarantined feedlot, a separate permit shall be required for the movement of such cattle from any such stockyard directly to a quarantined feedlot if that movement is interstate.

(c) *Movement of brucellosis exposed cattle other than in accordance with paragraphs (a) or (b) of this section.*

(1) Calves under 6 months of age which are being nursed by brucellosis exposed cows in a herd known to be affected with brucellosis, and which herd has been brucellosis tested within 10 days prior to the interstate movement of the calves, or calves under 6 months of age which have been weaned from brucellosis reactor or exposed cows not less than 30 days immediately preceding the interstate movement, may be moved interstate from any area into any area without restriction. Additionally official vaccinates under 12 months of age and steers and spayed heifers of any age in a herd known to be affected with brucellosis, but which is following an approved individual herd plan may be moved interstate from any area into any area without restrictions.

(2) Cattle that were moved interstate directly from a farm of origin to a specifically approved stockyard in accordance with the exception under § 78.9(b)(3)(iii) or (c)(3)(iii) and which have been subsequently determined to be brucellosis exposed animals, may be reshipped interstate directly back to the farm of origin under the following conditions:

(i) An authorized regulatory official of the State in which the animals are located and of the State to which the animals are to be moved advise Veterinary Services that such movement would not be contrary to the laws and regulations of their respective States;

(ii) The State to which the animals are to be moved agrees to quarantine the cattle on arrival and to provide for testing of all cattle on the farm of origin;

(iii) A permit for the shipment is obtained by the shipper from a Veterinary Services representative, State representative, or an accredited veterinarian upon a determination made by a Veterinary Services representative that the other conditions of this paragraph (§ 78.8(c)(2)) have been met; and

(iv) The cattle are accompanied to the farm of origin by such permit.

(Approved by the Office of Management and Budget under control number 0579-0064)

[47 FR 55652, Dec. 13, 1982, as amended at 48 FR 57472, Dec. 30, 1983]

§ 78.9 Cattle from herds not known to be affected with brucellosis.

Cattle from herds not known to be affected with brucellosis must be moved interstate in compliance with § 71.18 of this subchapter, except where specifically exempt, and then only as follows:

(a) *Class Free States.* Such cattle which originate in a Class Free State may be moved interstate without being tested for brucellosis under this subpart. They must be accompanied by a certificate, unless moved to immediate slaughter at a recognized slaughtering establishment, or to a specifically approved stockyard for sale to a recognized slaughtering establishment, or if moved in the course of normal ranching operations without change of ownership to another premises belonging to the same owner. The certificate must state, in addition to the items specified in § 78.1(n), that the cattle originated in a Class Free State.

(b) *Class A States.* If such cattle originate in a Class A State and are non-vaccinates under 18 months of age, or are official calfhood vaccinates of the beef breeds under 24 months of age, or are official calfhood vaccinates of the dairy breeds under 20 months of age, unless they are parturient or postparturient, may be moved interstate without being tested for brucellosis. If such cattle originate in a Class A State and are non-vaccinates over 18 months of age, are official calfhood vaccinates of the beef breeds over 24 months of age, are official calfhood vaccinates of the dairy breeds over 20 months of age, or if they are parturient or postparturient, they may only be moved interstate from such area under the conditions specified below:

(1) *Movement for immediate slaughter.* (i) Such cattle may be moved for immediate slaughter directly from a farm of origin to a recognized slaughtering establishment or directly through no more than one specifically approved stockyard and then directly to a recognized slaughtering establishment without being tested for brucellosis if identity to the farm of origin is maintained by means of identification tag numbers appearing on sale records showing the consignor or by penning animals from one farm apart from other animals.

(ii) Such cattle from other than a farm of origin may also be moved interstate directly to a recognized slaughtering establishment or through no more than one specifically approved stockyard and then directly to a recognized slaughtering establishment without being tested for brucellosis if identity to the Class A State is maintained by means of identification tag numbers appearing on sale records showing the consignor or by penning animals from one farm or state apart from other animals.

(2) *Movement to quarantined feedlots.* (i) Such cattle may be moved to a quarantined feedlot directly from a farm of origin or directly through no more than one specifically approved stockyard and then directly to a quarantined feedlot without being tested for brucellosis if identity to the farm of origin is maintained by means of identification tag numbers appearing on sale records showing the consignor or by penning animals from one farm apart from other animals.

(ii) Such cattle from other than a farm of origin may also be moved interstate directly to a quarantined feedlot or through no more than one specifically approved stockyard and then directly to a quarantined feedlot without being tested for brucellosis if identity to the Class A State is maintained by means of identification tag numbers appearing on sale records showing the consignor or by penning animals from one farm or State apart from other animals.

(3) *Movement other than in accordance with paragraphs (b) (1) and (2) of this section.* Such cattle may be moved interstate other than in accordance with paragraphs (b) (1) and (2) of this section only if:

(i) Such cattle originate in Certified Brucellosis-Free Herds and they are accompanied interstate by a certificate, which states, in addition to the items specified in § 78.1(n), that the cattle originated in a Certified Brucellosis-Free Herd; or

(ii) Such cattle are subjected to an official test for brucellosis and found negative for brucellosis within 30 days prior to such interstate movement, and accompanied interstate by a certificate, and the certificate shows in addition to items required under § 78.1(n), the test dates and results of the official brucellosis tests; or

(iii) Such cattle are moved directly from a farm of origin to a specifically approved stockyard and the owner causes such cattle to be subjected to an official test for brucellosis upon arrival at such stockyard prior to losing their identity with the farm of origin; or

(iv) Such cattle, if they are moved interstate in the course of normal ranching operations without change of ownership and to another premises belonging to the same owner, may be moved without testing and without a certificate.

(c) *Class B States.* If such cattle originate in a Class B State and are non-vaccinates under 18 months of age, or are official calfhood vaccinates of the beef breeds under 24 months of age, or are official calfhood vaccinates of the dairy breeds under 20 months of age, unless they are parturient or postparturient, they may be moved interstate without being tested for brucellosis. If such cattle originate in a Class B State and are non vaccinates over 18 months of age, or are official calfhood vaccinates of the beef breeds over 24 months of age, or are official calfhood vaccinates of the dairy breeds over 20 months of age, or if they are paturient or postparturient and under these ages, they may only be moved interstate from such area under the conditions specified below:

(1) *Movement for immediate slaughter.* (i) Such cattle may be moved for immediate slaughter directly from a farm of origin or a nonquarantined feedlot to a recognized slaughtering establishment or directly to a specifically approved stockyard for sale to a recognized slaughtering establishment without being "S" branded and without being accompanied by an "S" brand permit.

(ii) Such cattle from other than a farm of origin or a nonquarantined feedlot may also be moved interstate directly to a recognized slaughtering establishment if they are tested and found negative to an official test for brucellosis immediately prior to movement, or if they are "S" branded and accompanied by an "S" brand permit.

(iii) Such cattle from other than a farm of origin or a nonquarantined feedlot may also be moved for immediate slaughter without being "S" branded, if they are accompanied by a VS Form 1-27 permit and are moved in vehicles closed with official seals. Official seals shall only be applied or removed by a Veterinary Services representative, a State representative, an accredited veterinarian, or by other persons authorized for this purpose by the Veterinary Services representatives.

(2) *Movement to quarantined feedlots.* (i) Such cattle may be moved to a quarantined feedlot directly from a farm of origin without being "S" branded and without being accompanied by an "S" brand permit if such cattle are "S" branded upon arrival at the quarantined feedlot, or directly from a farm of origin to a specifically approved stockyard for sale to a quarantined feedlot without being "S" branded and without beng accompanied by an "S" brand permit.

(ii) Such cattle from other than a farm of origin may also move interstate directly to a quarantined feedlot if they are tested and found negative to an official test immediately prior to the movement, or if they are "S" branded and accompanied by an "S" brand permit.

(3) *Movement other than in accordance with paragraphs (c) (1) and (2) of this section.* Such cattle may be moved interstate other than in accordance with paragraphs (c) (1) and (2) of this section only if:

(i) Such cattle originate in Certified Brucellosis-Free Herds and they are accompanied interstate by a certificate, which states, in addition to the items specified in § 78.1(n), that the cattle originated in a Certified Brucellosis-Free Herd; or

(ii) Such cattle are subjected to an official test for brucellosis and found negative for brucellosis within 30 days prior to interstate movement, are accompanied interstate by a certificate which shows, in addition to items required under § 78.1(n), the test dates and results of the official brucellosis tests, and if such cattle are accompanied interstate by a "Permit for Entry"; or

(iii) Such cattle are moved directly from a farm of origin to a specifically approved stockyard and the owner causes such cattle to be subjected to an official test for brucellosis upon arrival at such stockyard, but prior to losing their identity to the farm of origin. Such cattle shall be accompanied by a certificate which shows, in addition to the items required under § 78.1(n), the dates and results of any official test required by this paragraph and shall be accompanied by a "Permit for Entry"; or

(iv) Such cattle originate from herds in which: (A) All the cattle were subjected to a complete herd test for brucellosis within 12 months of the date of the interstate movement; (B) any cattle which were added to the herd subsequent to such complete herd test were tested and found negative to an official test for brucellosis within 30 days prior to the date the cattle were added to the herd; (C) the cattle subject to the complete herd test have not changed ownership from the date of such test; and (D) none of the cattle in the herd have come in contact with any other cattle which have not been tested as prescribed in this subparagraph; or

(v) The requirement of § 78.9(b)(3)(iv) may be waived with the written concurrence of the State animal health officials of each involved State in the case of animals moving interstate in the course of normal ranching operations without change of ownership and to another premises belonging to the same owner.

(d) *Class C State.* If such cattle originate in a Class C State and are nonvaccinates under 18 months of age, or are official calfhood vaccinates of the beef breeds under 24 months of age, or are official calfhood vaccinates of the dairy breeds under 20 months of age, they may be moved interstate without restrictions under this subpart, unless they are parturient or postparturient. If such cattle originate in a Class C State and are nonvaccinates over 18 months of age, or are official calfhood vaccinates of the beef breeds over 24 months of age, or are official calfhood vaccinates of the dairy breeds over 20 months of age, or if they are parturient or postparturient and under these ages, they may only be moved interstate from such area under the conditions specified below:

(1) *Movement for immediate slaughter.* (i) Such cattle from Certified Brucellosis-Free Herds may move to recognized slaughtering establishments or to specifically approved stockyards for sale for movement to immediate slaughter at a recognized slaughtering establishment without being tested for brucellosis if identity to the Certified Brucellosis-Free Herd is maintained.

(ii) Such cattle may be moved for immediate slaughter directly from a farm of origin or a nonquarantined feedlot to a recognized slaughtering establishment or to a specifically approved stockyard for sale for movement to a recognized slaughtering establishment without being "S" branded and without being accompanied by a "S" brand permit.

(iii) Such cattle from other than a farm of origin or a nonquarantined feedlot may also be moved interstate directly to a recognized slaughtering establishment, if they have been tested negative within 30 days prior to movement, or if they are "S" branded and are accompanied by an "S" brand permit.

(iv) Such cattle from other than a farm of origin or a nonquarantined feedlot may also be moved interstate for immediate slaughter to a recognized slaughtering establishment without being "S" branded, if they are accompanied by a VS Form 1-27 permit and are moved in vehicles closed with official seals. Official seals shall only be applied or removed by a Veterinary Services representative, a State representative, an accredited veterinarian, or by other persons authorized for this purpose by the Veterinary Services representatives.

(2) *Movement to quarantined feedlots.* (i) Such cattle may be moved to a quarantined feedlot directly from a farm of origin without being "S" branded and without being accompanied by an "S" brand permit if such cattle are "S" branded upon arrival at the quarantined feedlot, and such cattle may be moved directly from a farm of origin to a specifically approved stockyard for sale to a quarantined feedlot without being "S" branded and without being accompanied by an "S" brand permit.

(ii) Such cattle from other than a farm of origin may also move interstate directly to a quarantined feedlot if they have been tested negative within 30 days prior to movement, or if they are "S" branded and accompanied by an "S" brand permit.

(3) *Movement other than in accordance with paragraphs (d) (1) or (2) of this section.* Such cattle may be moved other than in accordance with paragraph (d) (1) or (2) of this section only if:

(i) Such cattle originate in Certified Brucellosis-Free Herds and they are accompanied interstate by a certificate which states, in addition to the items specified in § 78.1(n), that the cattle originated in a Certified Brucellosis-Free Herd; or

(ii) Such cattle are under 18 months of age or such cattle are official vaccinates of the beef breeds under 24 months of age or of the dairy breeds under 20 months; or

(iii) Such cattle have been subjected to two consecutive official negative tests for brucellosis with the first test not less than 60 days before interstate movement and the second test not less than 60 days after the first test nor more than 30 days before the date of the interstate movement, provided however, that the time period for the first test is valid up to 12 months.

These tested cattle shall be accompanied by a certificate which shows, in addition to the items required under § 78.1(n), the dates and results of the official tests required by this paragraph and shall be accompanied by a "Permit for Entry;" or

(iv) Such cattle are official vaccinates of the beef breeds over 24 months of age or of the dairy breeds over 20 months of age, have been subjected to an official test for brucellosis not more than 30 days before the date of interstate movement, and such cattle are accompanied by a certificate which shows in addition to the items required under § 78.1(n), the date and results of the official test required by this paragraph, and shall be accompanied by a "Permit for Entry;" or

(v) Such cattle have been subjected to an official negative test for brucellosis not less than 60 days nor more than 1 year before the interstate movement, are moved directly from a farm of origin to a specifically approved stockyard and the owner causes such cattle to be subjected to an official test for brucellosis upon arrival at such stockyard, but prior to losing their identity to the farm of origin. These cattle shall be accompanied by a document which shows the date and results of the official test required to be administered prior to interstate movement; or

(vi) Such cattle which are official vaccinates of the beef breeds over 24 months of age or of the dairy breeds over 20 months of age, are moved directly from a farm of origin to a specifically approved stockyard and the owner causes such cattle to be subjected to an official test for brucellosis upon arrival at such stockyard, but prior to losing their identity to the farm of origin. These cattle shall be accompanied interstate by a document which shows the date of vaccination; or

(vii) Such cattle originate from herds in which:

(A) All the cattle were subjected to a complete herd test for brucellosis within 12 months of the date of the interstate movement;

(B) Any cattle which were added to the herd subsequent to such complete herd test were tested and found negative to an official test for brucellosis within 30 days prior to the date the cattle were added to the herd;

(C) The cattle subject to the complete herd test have not changed ownership from the date of such test; and

(D) None of the cattle in the herd have come in contact with any other cattle which have not been tested as prescribed in this paragraph.

[47 FR 55653, Dec. 13, 1982]

§§ 78.10—78.11 [Reserved]

§ 78.12 Other movements.

The Deputy Administrator, Veterinary Services, may upon request, in specific cases, permit the interstate movement not otherwise provided for in this subpart of cattle under such conditions as he may prescribe in each case to prevent the spread of brucellosis. The Deputy Administrator, Veterinary Services, will promptly notify the appropriate livestock sanitary official of the States involved of any such action.

§ 78.12a Cattle from quarantined areas.

Notwithstanding any provisions in the regulations to the contrary, cattle may be moved interstate from a quarantined area only in accordance with the provisions of this section.

(a) *Steers and spayed heifers.* Steers and spayed heifers may be moved interstate without restriction.

(b) *Brucellosis reactor cattle.* Brucellosis reactor cattle may be moved in accordance with the provisions of § 78.7.

(c) *Brucellosis exposed cattle.* Brucellosis exposed cattle may be moved in accordance with the provisions of § 78.8 (a) or (b).

(d) *Movement from qualified herds.* Cattle from qualified herds in any quarantined area may be moved interstate only as follows:

(1) *Movement for immediate slaughter.* (i) Such cattle may move for immediate slaughter directly from a farm of origin to a recognized slaughtering establishment or directly from a farm of origin through no more than one specifically approved stockyard and then directly to a recognized slaughtering establishment and they

are accompanied by a certificate, are subjected to an official test for brucellosis and found negative within 30 days prior to such interstate movement and the certificate shows, in addition to items required under § 78.1(n), the test dates and results of the official brucellosis test; or (ii) Such cattle are moved in accordance with the provisions of § 78.8(a); or

(2) *Movement to quarantined feedlots.* (i) Such cattle may move to a quarantined feedlot directly from a farm of origin or directly from a farm of origin through no more than one specifically approved stockyard and then directly to a quarantined feedlot if they are accompanied by a certificate, are subjected to an official test for brucellosis and found negative within 30 days prior to such interstate movement and the certificate shows, in addition to items required under § 78.1(n), the test dates and results of the official brucellosis test; or (ii) Such cattle are moved in accordance with the provisions of § 78.8(b).

(3) *Movement other than in accordance with paragraph (d) (1) or (2) of this section.* Such cattle may be moved other than in accordance with paragraph (d) (1) or (2) of this section, either directly from a farm of origin or through no more than one specifically approved stockyard, if the cattle are accompanied by a certificate and the cattle, except official vaccinates less than 12 months of age and calves less than 6 months of age, are subjected to an official test for brucellosis and found negative within 30 days prior to such interstate movement, and the certificate shows, in addition, to items required under § 78.1(n), the test dates and results of the official brucellosis test.

(e) *Movement from herds of unknown status.* Cattle which originate in herds of unknown status in a quarantined area may be moved interstate only for immediate slaughter or directly to a quarantined feedlot in accordance with § 78.8 (a) or (b).[4]

[40 FR 59421, Dec. 24, 1975, as amended at 44 FR 55807, Sept. 28, 1979; 50 FR 11500, Mar. 22, 1985]

Subpart C—Restrictions on Interstate Movement of Bison Because of Brucellosis

§ 78.13 General restrictions.

Bison may not be moved interstate except in compliance with the regulations in this subpart.

§ 78.14 Bison steers and spayed heifers.

Bison steers and spayed heifers over 6 months of age may be moved interstate from any area without restriction under this subpart.

§ 78.15 Brucellosis reactor bison.

Brucellosis reactor bison may only be moved interstate for immediate slaughter directly to a recognized slaughtering establishment or directly from a farm of origin through no more than no specifically approved stockyard and then directly to such a slaughtering establishment, and only in accordance with the following requirements:

(a) *Marking of brucellosis reactor bison.* Brucellosis reactor bison shall be marked for identification by branding the letter "B" on the left jaw in letters not less than 2 nor more than 3 inches high, and attaching to the left ear a metal tag bearing a serial number and the inscription "U.S. Reactor," or a similar State reactor tag.

(b) *Required permit.* Brucellosis reactor bison shall be accompanied to destination by a permit for movement of the animals in accordance with § 78.3.

(c) *Marking of records.* Each transportation agency moving brucellosis reactor bison in the course of their interstate movement shall plainly write or stamp upon the face of each waybill, conductor's manifest, switch order, vehicle interchange record, or other document which it prepares in connection with such movement, the words "Brucellosis Reactors."

(d) *Segregation of brucellosis reactor bison en route interstate.* Brucellosis reactor bison shall not be moved interstate in a railroad car, boat, truck, or other means of conveyance containing non-reactor animals susceptible to brucellosis, unless all of the animals are for immediate slaughter, or unless the reactor bison are kept separate from the other animals by a partition securely affixed to the sides of the means of conveyance.

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[4] A herd of unknown status in a quarantined area may become a qualified herd upon compliance with the provisions of § 78.1(nn).

[40 FR 17816, Apr. 22, 1975, as amended at 44 FR 55807, Sept. 28, 1979]

§ 78.16 Brucellosis exposed bison.

Brucellosis exposed bison may be moved interstate from any area only as follows:

(a) *Movement of brucellosis exposed bison to quarantined feedlots.* Such bison are moved directly to a quarantined feedlot or directly from a farm of origin through no more than one specifically approved stockyard and then directly to a quarantined feedlot. Such bison shall be accompanied by a permit. If the movement is through a specifically approved stockyard to a quarantined feedlot, a separate permit shall be required for the subsequent interstate movement of the bison from the stockyard to the quarantined feedlot, or

(b) *Movement of brucellosis-exposed bison for immediate slaughter.* Such bison are moved directly to a recognized slaughtering establishment or directly from a farm of origin through no more than one specifically approved stockyard and then directly to such a slaughtering establishment. Such bison shall be accompanied by a permit. If the movement is through a specifically approved stockyard to a slaughtering establishment, a separate permit shall be required for the subsequent interstate movement of the bison from the stockyard to the recognized slaughtering establishment.

(c) *Movement of brucellosis exposed bison other than in accordance with paragraph (a) or (b) of this section.* Bison calves under 6 months of age which are being nursed by brucellosis exposed bison cows in a herd known to be affected with brucellosis, and which herd has been brucellosis tested within 10 days prior to the interstate movement of the calves, or bison calves under 6 months of age which have been weaned from brucellosis reactor or exposed bison cows for not less than 30 days immediately preceding the interstate movement, may be moved interstate from any area into any area without restriction. Additionally, official vaccinates under 12 months of age and steers and spayed heifers of any age in a herd known to be affected but which is following an approved individual herd plan may be moved interstate from any area into any area without restrictions.

[44 FR 55807, Sept. 28, 1979, as amended at 47 FR 55655, Dec. 13, 1982]

§ 78.17 Bison from herds not known to be affected with brucellosis.

Bison from herds not known to be affected with brucellosis may be moved interstate from any area only as follows:

(a) *Movement for immediate slaughter.* Such bison are so moved for immediate slaughter, or

(b) *Movement to quarantined feedlot.* Such bison are so moved to a quarantined feedlot.

(c) *Movement other than in accordance with paragraphs (a) or (b) of this section.* Such bison may be moved other than in accordance with paragraphs (a) or (b) of this action only as follows:

(1) Such bison calves under 6 months of age may be so moved when accompanied by a certificate.

(2) Such officially vaccinated bison under 24 months of age which are not parturient (springers) or postparturient may be so moved when accompanied by a certificate.

(3) Such bison from a herd which has been declared free of brucellosis by the cooperating State and Federal livestock sanitary officials of the State in which the herd is located may be moved when accompanied by a certificate.

(4) Other such bison may be so moved if they are accompanied by a certificate, are subjected to an official test for brucellosis and found negative within 30 days prior to such interstate movement and the certificate shows in addition to items required under § 78.1(n), the dates of the official test and the results of the official brucellosis test.

[40 FR 17816, Apr. 22, 1975, as amended at 44 FR 55807, Sept. 28, 1979; 50 FR 11500, Mar. 22, 1985]

§ 78.18 Movement of bison from public zoo to public zoo.

Bison from herds not known to be affected with brucellosis and shipped from a zoo owned by a governmental agency to another such zoo may be moved interstate from any area if handled in accordance with § 78.4.

§ 78.19 Other movements.

The Deputy Administrator, Veterinary Services, may upon request in specific cases, permit the interstate movement not otherwise provided for in this subpart of bison under such conditions as he may prescribe in each case to prevent the spread of brucellosis. The Deputy Administrator, Veterinary Services, will promptly notify the appropriate livestock sanitary official of the States involved of any such action.

Subpart D—Designation of Brucellosis Areas and Specifically Approved Stockyards

§ 78.20 State/area classifications.

(a) *Class Free.* Alaska; Connecticut; Delaware; Hawaii; Maine; Maryland; Massachusetts; Michigan; Minnesota; Montana; New Hampshire; New York; North Carolina; North Dakota; Pennsylvania; Rhode Island; South Carolina; Utah; Vermont; Virgin Islands; Wisconsin; and Wyoming.

(b) *Class A.* Arizona, California, Colorado, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Nebraska, New Jersey, New Mexico, Ohio, Oregon, Puerto Rico, South Dakota, Tennessee, Virginia, Washington, and West Virginia.

(c) *Class B.* Alabama, Florida (Counties of Alachua, Baker, Bay, Bradford, Calhoun, Clay, Columbia, Dixie, Duval, Escambia, Franklin, Gadsden, Gilchrist, Gulf, Hamilton, Holmes, Jackson, Jefferson, Lafayette, Leon, Liberty, Madison, Nassau, Okaloosa, Putnam, Saint Johns, Santa Rosa, Suwannee, Taylor, Union, Wakulla, Walton, and Washington), Kentucky, Mississippi, Missouri, Nevada, Oklahoma, Texas (Counties of Andrews, Archer, Armstrong, Bailey, Bandera, Baylor, Bell, Blanco, Borden, Bosque, Brewster, Briscoe, Brown, Burnet, Callahan, Carson, Castro, Childress, Clay, Cochran, Coke, Coleman, Collingsworth, Comal, Comanche, Concho, Cooke, Coryell, Cottle, Crane, Crockett, Crosby, Culberson, Dallam, Dawson, Deaf Smith, Dickens, Donley, Eastland, Ector, Edwards, El Paso, Erath, Fisher, Floyd, Foard, Gaines, Garza, Gillespie, Glasscock, Gray, Hale, Hall, Hamilton, Hansford, Hardeman, Hartley, Haskell, Hays, Hemphill, Hockley, Hood, Howard, Hudspeth, Hutchinson, Irion, Jack, Jeff Davis, Johnson, Jones, Kendall, Kent, Kerr, Kimble, King, Kinney, Knox, Lamb, Lampasas, Lipscomb, Llano, Loving, Lubbock, Lynn, McCullock, Martin, Mason, Maverick, Medina, Menard, Midland, Mills, Mitchell, Montague, Moore, Motley, Nolan, Ochiltree, Oldham, Palo Pinto, Parker, Parmer, Pecos, Potter, Presidio, Randall, Reagan, Real, Reeves, Roberts, Runnels, San Saba, Schleicher, Scurry, Shackelford, Sherman, Somervell, Sterling, Stephens, Stonewall, Sutton, Swisher, Tarrant, Taylor, Terrell, Terry, Throckmorton, Tom Green, Travis, Upton, Uvalde, Val Verde, Ward, Wheeler, Wichita, Wilbarger, Williamson, Winkler, Wise, Yoakum, Young and Zavala).

(d) *Class C.* Arkansas, Florida (Counties of Brevard, Broward, Charlotte, Citrus, Collier, Dade, De Soto, Flagler, Glades, Hardee, Hendry, Hernando, Highlands, Hillsborough, Indian River, Lake, Lee, Levy, Manatee, Marion, Martin, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pasco, Pinellas, Polk, Saint Lucie, Sarasota, Seminole, Sumter, and Volusia), Louisiana, and Texas (Counties of Anderson, Angelina, Aransas, Atascosa, Austin, Bastrop, Bee, Bexar, Bowie, Brazoria, Brazos, Brooks, Burleson, Caldwell, Calhoun, Cameron, Camp, Cass, Chambers, Cherokee, Collin, Colorado, Dallas, Delta, Denton, DeWitt, Dimmit, Duval, Ellis, Falls, Fannin, Fayette, Fort Bend, Franklin, Freestone, Frio, Galveston, Goliad, Gonzales, Grayson, Gregg, Crimes, Guadalupe, Hardin, Harris, Harrison, Henderson, Hidalgo, Hill, Hopkins, Houston, Hunt, Jackson, Jasper, Jefferson, Jim Hogg, Jim Wells, Karnes, Kaufman, Kenedy, Kleberg, Lamar, LaSalle, Lavaca, Lee, Leon, Liberty, Limestone, Live Oak, McLennan, McMullen, Madison, Marion, Matagorda, Milam, Montgomery, Morris, Nacogdoches, Navarro, Newton, Nueces, Orange, Panola, Polk, Rains, Red River, Refugio, Robertson, Rockwall, Rusk, Sabine, San Augustine, San Jacinto, San Patricio, Shelby, Smith, Starr, Titus, Trinity, Tyler, Upshur, Van Zandt, Victoria, Walker, Waller, Washington, Webb, Wharton, Willacy, Wilson, Wood and Zapata).

[47 FR 55655, Dec. 13, 1982, as amended at 48 FR 34944, Aug. 2, 1983; 49 FR 3449, Jan. 27, 1984; 49 FR 3979, Feb. 1, 1984; 49 FR 20643, May 16, 1984; 49 FR 45111, Nov. 15, 1984; 49 FR 46872, Nov. 29, 1984; 50 FR 5548, Feb. 11, 1985; 50 FR 9992, Mar. 13, 1985; 50 FR 10493, Mar. 15, 1985; 50 FR 13547, Apr. 5, 1985; 50 FR 15411, Apr. 18, 1985; 50 FR 10493, Mar. 15, 1985; 50 FR 13547, Apr. 5, 1985; 50 FR 15411, Apr. 18, 1985; 50 FR 19164, Mar. 7, 1985; 50 FR 23394, June 4, 1985; 50 FR 23938; June 7, 1985; 50 FR 28899, July 17, 1985; 50 FR 39076, Sept. 27, 1985; 50 FR 39650, Sept. 30, 1985; 50 FR 40800, Oct. 7, 1985; 50 FR 45809, Nov. 4, 1985]

§ 78.21 [Reserved]

§ 78.22 Quarantined areas.

Notice is hereby given that because of the existence of the contagion of brucellosis and the nature and extent of such contagion in certain areas which do not have control and eradication procedures adequate to prevent the interstate dissemination of the disease, the following areas are quarantined:

None.

[47 FR 55655, Dec. 13, 1982]

§ 78.23 Specifically approved stockyards.

Notices containing lists of stockyards specifically approved for the purposes of the regulations in this part are published in the FEDERAL REGISTER. Information with respect to these stockyards may also be obtained from Veterinary Services representatives and State inspectors.

§ 78.24 Slaughtering establishments.

(a) Information with respect to the slaughtering establishments operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), may be obtained from the Meat and Poultry Inspection Program, Animal and Plant Health Inspection Service, United States Department of Agriculture, Washington, D.C. 20250, and from the Veterinary Services representative or a State representative.

[40 FR 17816, Apr. 22, 1975, as amended at 44 FR 55808, Sept. 28, 1979]

§ 78.25 Designations of States/Areas and approved stockyards.

(a) The Deputy Administrator, Veterinary Services, is authorized to amend § 78.20 to reclassify States and Areas from a lower class as Class Free, Class A, Class B, or Class C, when he determines that the areas come within the appropriate definitions in § 78.1 (t), (u), (v), or (w). In the case of any reclassification to a lower class, the State animal health official of the State involved will be notified of such downgrading, and shall be given an opportunity to request an administrative review and to present his objections and arguments to the Deputy Administrator prior to the downgrading taking effect.

(b) The Deputy Administrator is authorized to specifically approve stockyards for the purposes of the regulations in this part and to promulgate notices listing such stockyards in accordance with § 78.23 when he determines that the inspection and handling of livestock at such stockyards are adequate to effectuate the purposes of the regulations in this part and that Veterinary Services and the State in which such stockyards are located have entered into a Memorandum of Understanding setting forth certain standards for such stockyards. The Deputy Administrator may withdraw approval and remove any stockyard from the said list when he finds that the inspection or handling of livestock at such stockyard is no longer adequate to effectuate the purposes of such regulations, or when he determines that there is not full compliance with all provisions of the standards involved, or when such Memorandum of Understanding between Veterinary Services and the State within which such stockyard is located has been terminated.

(c) Before the Deputy Administrator withdraws specific approval and removes any specifically approved stockyard from the approved lists, the owner of such establishment shall be given notice by the Deputy Administrator of the charges against him and shall have an opportunity to present his views thereon. In those instances where there is a conflict as to the facts, a hearing shall be held to resolve such conflicts.

[40 FR 17816, Apr. 22, 1975, as amended at 44 FR 55808, Sept. 28, 1979; 47 FR 55655, Dec. 13, 1982]

Subpart E—Restrictions on Movement of Swine Because of Brucellosis

SOURCE: 42 FR 64340, Dec. 23, 1977, unless otherwise noted.

§ 78.26 General restrictions

Breeding swine, sows, boars, brucellosis reactor swine, and brucellosis exposed swine may not be moved interstate or in interstate commerce except in compliance with the regulations in this subpart.

[43 FR 11144, Mar. 17, 1978, as amended at 50 FR 45987, Nov. 6, 1985]

§ 78.27 Brucellosis reactor swine.

Brucellosis reactor swine may only be moved interstate under this section for immediate slaughter directly to a slaughtering establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or directly to a State inspected slaughtering establishment, or directly to a stockyard posted under the provisions of the Packers and Stockyards Act, as amended (7 U.S.C. 181 et seq.) or directly to a market agency or dealer registered under said Packers and Stockyards Act, for sale to such a slaughtering establishment in accordance with the following requirements:

(a) *Marking of brucellosis reactor swine.* Brucellosis reactor swine shall be identified by attaching up to the left ear a metal tag bearing a serial number and the inscription "U.S. Reactor" or a similar State reactor tag.

(b) *Permit required.* Brucellosis reactor swine shall be accompanied to destination by a permit for movement of the animals in accordance with the provisions of § 78.3.

(c) *Marking of records.* Each transportation agency moving brucellosis reactor swine in the course of their interstate movement shall plainly write or stamp upon the face of each waybill, conductor's manifest, switch order, vehicle interchange record, or other document, which it prepares in connection with such movement, the words "Brucellosis Reactor Swine."

(d) *Segregation of brucellosis reactor swine en route interstate.* Brucellosis reactor swine shall not be moved interstate in a railroad car, boat, truck, or other means of conveyance, containing nonreactor animals susceptible to brucellosis, unless all of the animals in the shipment are for immediate slaughter, or unless the reactor swine are kept separate from all other animals by a partition securely affixed to the sides of the means of conveyance.

[42 FR 64340 Dec. 23, 1977, as amended at 43 FR 11144, Mar. 17, 1978]

§ 78.28 Brucellosis exposed swine.

Brucellosis exposed swine may be moved interstate only for immediate slaughter directly to a slaughtering establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or directly to a State inspected slaughtering establishment, or directly to a stockyard posted under the provisions of the Packers and Stockyards Act, as amended (7 U.S.C. 181 et seq.) or directly to a market agency or dealer registered under said Packers and Stockyards Act, for sale to such a slaughtering establishment, if such swine are accompanied by a permit as defined in paragraph 78.1(v).

[43 FR 11144, Mar. 17, 1978]

§ 78.29 Brucellosis testing of breeding swine.

(a) Breeding swine from Validated Brucellosis Free Herds and Validated Brucellosis Free Areas may be moved interstate for other than slaughter only if they are accompanied by a certificate and the certificate states that they originated in either a Validated Brucellosis Free Herd or in a Validated Brucellosis Free area.

(b) Breeding swine from nonvalidated brucellosis free herds in nonvalidated brucellosis free areas may be moved interstate for other than slaughter only if they have been officially tested negative for brucellosis and found to be negative within 30 days prior to interstate movement and are accompanied interstate by a certificate which shows, in addition to items required under § 78.1(n), the dates and the results of the official brucellosis test.

[47 FR 55656, Dec. 13, 1982]

§ 78.30 Identification of sows and boars.

(a) *Sows and boars sold for slaughter or for sale for slaughter.* To provide for traceback to their herd of origin, all sows and boars moved in interstate commerce for slaughter or for sale for slaughter shall be identified to the herd of origin by a Veterinary Services approved tattoo code applied[6, 7] to the back of each swine prior to such movement in interstate commerce and before they are mixed with swine from any other source; *Provided,* That upon written request from a State Animal Health official of a State, the Area Veterinarian in Charge of that State may authorize the use of Veterinary Services approved swine identification tags[9] on sows and boars instead of or in addition to the tattoo when such approved swine identification tag[9] is determined by him to be necessary to provide for traceback to the herd of origin. However, sows and boars may be moved in interstate commerce, without such prior identification, directly from a herd of origin to a slaughtering establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), or a State inspected slaughtering establishment, or to a stockyard posted under the provisions of the Packers and Stockyards Act, as amended (7 U.S.C. 181 et seq.), or a market agency or dealer registered under said Packers and stockyards Act, if such swine are identified to the herd of origin by a Veterinary Services approved swine identification tag[9] or approved tattoo code applied[7] to the back of each swine upon arrival thereat and before they are mixed with swine from any other source.[8]

(b) *Breeding swine.* To provide for traceback to their herd of origin, all breeding swine moved in interstate commerce for any purpose shall be individually identified to the herd of origin by a Veterinary Services approved swine identification tag[9] prior to such movement in interstate commerce and before they are mixed with swine from any other source, and such swine shall be accompanied by an owner's statement or other document as defined in § 78.1(w) or (dd) and which shall be delivered by the carrier to the consignee.[10] Further, registered

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[6] [Reserved]

[7] Veterinary Services approved tattoo codes will be assigned to owners, market agencies, dealers, and other persons upon application to the State Animal Health official or the Area Veterinarian in Charge, Veterinary Services, Animal and Plant Health Inspection Service, for the State in which such owner, market agency, dealer, or other person maintains his principal place of business.

[8] It is requested that the operator of each livestock concentration point, slaughter establishment or other place of business where such swine are identified on arrival in accordance with this section, enter such identification on the yarding receipt, sale ticket, invoice, waybill, or similar document relating to the swine, and that such document be maintained on file at the place of business for at least one year and be made available for inspection during ordinary business hours upon request by a Veterinary Services or State inspector.

[9] Serial numbers of approved swine identification tags to be used will be assigned to owners, market agencies, dealers, and other persons upon application to the State Animal Health official or the Area Veterinarian in Charge, Veterinary Services, Animal and Plant Health Inspection Service, for the State in which such owner, market agency, dealer or other person maintains his place of business.

[10] It is requested that the operator of each livestock concentration point or other place of business where such swine are identified upon arrival in accordance with this section, enter such identification on the yarding receipt, sale ticket, invoice, waybill, or similar document relating to the swine and that such documents be maintained on file at the

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swine may be identified in the same manner as recorded with the particular registry association in lieu of the approved swine identification tag.[9]

(c) Each person who ships, transports, or otherwise causes the swine to be moved in interstate commerce is responsible for the identification of the swine as required by this section.

(d) No person shall remove or tamper with or cause the removal of or tampering with a tattoo, approved swine identification tag, or other identification device required to be on swine pursuant to this section while such swine are being moved in interstate commerce, except at the time of slaughter, or as may be authorized by the Deputy Administrator upon request in specific cases and under such conditions as the Deputy Administrator may impose to ensure continuing identification.

[42 FR 64340, Dec. 23, 1977, as amended at 50 FR 45987, Nov. 6, 1985]

§ 78.31 Other movements.

The Deputy Administrator, Veterinary Services, may upon request, in specific cases, permit the interstate movement not otherwise provided for in this subpart of swine under such conditions as he may prescribe in each case to prevent the spread of brucellosis. The Deputy Administrator, Veterinary Services, will promptly notify the appropriate livestock sanitary official of the States involved of any such action.

PART 79—SCRAPIE IN SHEEP

Sec.
79.1 Definitions.
79.2 Notice of quarantine.
79.3 General restriction.
79.4 Movement of sheep from and through a quarantined area.
79.5 Disinfection of facilities.

AUTHORITY: Secs. 4-7, 23 Stat. 32, secs. 1, 2, 32 Stat. 791, secs. 1-4, 33 Stat. 1264; 21 U.S.C. 111-113, 115, 117, 120, 121, 123-126.

SOURCE: 28 FR 5960, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

§ 79.1 Definitions.

As used in this part, the following terms shall have the meanings set forth in this section.

(a) *Veterinary Services.* The term "Veterinary Services" means the Veterinary Services unit of the Animal and Plant Health Inspection Service of the United States Department of Agriculture.

(b) *Deputy Administrator, Veterinary Services.* The term "Deputy Administrator, Veterinary Services" means the Deputy Administrator, Veterinary Services or any other official of Veterinary Services to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(c) *Veterinary Services inspector.* The term "Veterinary Services inspector" means an inspector of the Veterinary Services.

(d) *Person.* The term "person" means any person, company or corporation.

(e) *Moved.* The term "moved" means transported, shipped, delivered or received for transportation, driven on foot or caused to be driven on foot, by any person.

(f) *State.* Any State, Territory, the District of Columbia, or Puerto Rico.

(g) *Interstate.* From one State into or through any other State.

[28 FR 5960, June 13, 1963, as amended at 29 FR 14490, Oct. 22, 1964]

§ 79.2 Notice of quarantine.

(a) Notice is hereby given that the contagion or vectors of scrapie, a contagious, infectious and communicable disease, exist in the following areas or that sheep affected with scrapie exist in the following areas, and, therefore,

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place of business for at least one year and be made available for inspection during ordinary business hours upon request by a Veterinary Services or State inspector. It is further requested that the official inspection certificate or other document required by this section to accompany certain swine interstate be maintained on file at the farm or other place of business of the consignee for at least one year and be made available for inspection during ordinary business hours upon request by a Veterinary Services or State inspector.

the following areas are hereby quarantined because of said disease:

(1) [Reserved]

(Sec. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132 (21 U.S.C. 111-113, 115, 117, 120, 121, 123-126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141)

[45 FR 6083, Jan. 25, 1980, as amended at 47 FR 42719, Sept. 29, 1982]

§ 79.3 General restriction.

No sheep shall be moved interstate from or through any quarantined area except as provided in the regulations in this part.

§ 79.4 Movement of sheep from and through a quarantined area.

(a) Sheep that have been directly exposed to scrapie may be moved interstate for immediate slaughter from any quarantined area under conditions prescribed in advance by a Veterinary Services inspector in each instance, to an establishment approved for that purpose by the Deputy Administrator, Veterinary Services, if such sheep are not infected with scrapie at the time of such movement.

(b) Sheep of flocks in a quarantined area which upon inspection are found not to show evidence of being infected with scrapie, and insofar as can be determined have not been exposed thereto, may be moved interstate for any purpose. Such inspection shall be made by a Veterinary Services inspector and sheep so moved shall be accompanied by a certificate from such inspector showing that the sheep are free from scrapie and other contagious or communicable diseases and insofar as can be determined such sheep have not been exposed to scrapie or other contagious or communicable diseases.

(c) The Deputy Administrator, Veterinary Services may authorize the movement of sheep not infected with scrapie which is not otherwise authorized by this section under such conditions as he may prescribe to prevent the spread of scrapie.

(d) Sheep may be moved in direct transit between points outside the quarantined area through any such quarantined area without restriction under this part.

§ 79.5 Disinfection of facilities.

Railroad cars, trucks, boats, aircraft and other means of conveyance, and all other facilities, including facilities for feeding, watering, and resting sheep, which are used in connection with the interstate movement of sheep from a quarantined area shall be thoroughly cleaned and disinfected immediately after each such use. Sodium hydroxide (Lye) prepared in a fresh solution in the proportion of not less than 1 pound avoirdupois of sodium hydroxide of not less than 95 percent purity to 6 gallons of water, or one 13½-ounce can to 5 gallons of water,[1] shall be used in such disinfection.

[36 FR 10844, June 4, 1971]

PART 80—PARATUBERCULOSIS IN DOMESTIC ANIMALS

Sec.

80.1 Definitions.

80.2 Notice relating to existence of paratuberculosis.

80.3 General restrictions.

80.4 Movement of paratuberculosis reactors.

80.5 Reshipment of purebred paratuberculosis reactors.

80.6 Marking of records.

80.7 Cleaning and disinfecting vehicles.

80.8 Segregation of paratuberculosis reactors en route interstate.

80.9 Certificates pertaining to movement of animals.

AUTHORITY: Secs. 4-7, 23 Stat. 32, as amended, secs. 1, 2, 32 Stat. 791, as amended, 792, as amended, sec. 3, 33 Stat. 1265, as amended, sec. 13, 65 Stat. 693; 21 U.S.C. 111-113, 114a-1, 115, 117, 120, 121, 125, unless otherwise noted.

SOURCE: 28 FR 5961, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

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[1] Due to the extremely caustic nature of sodium hydroxide solution, precautionary measures such as the wearing of rubber gloves, boots, raincoat, and goggles should be observed. An acid solution such as vinegar should be kept readily available in case any of the sodium hydroxide solution should come in contact with the body.

§ 80.1 Definitions.

As used in this part, the following terms shall have the meanings set forth in this section except as otherwise clearly indicated.

(a) *Paratuberculosis.* The infectious and communicable disease of domestic animals commonly known as Johne's disease and paratuberculosis.

(b) *State.* Any State, Territory, the District of Columbia, or Puerto Rico.

(c) *Interstate.* From one State into or through any other State.

(d) *Person.* Any person, company, or corporation.

(e) *Moved.* Shipped, transported or otherwise moved, or delivered or received for movement, by any person.

(f) [Reserved]

(g) *Federal inspector.* An inspector of the Animal and Plant Health Inspection Service, United States Department of Agriculture, responsible for the performance of the function involved.

(h) *State inspector.* An inspector regularly employed in livestock sanitary work of a State or political subdivision thereof, and who is authorized by such State or political subdivision to perform the function involved.

(i) *Accredited veterinarian.* A veterinarian approved by the United States Department of Agriculture to perform the function involved.

(j) *Specifically approved stockyard.* A stockyard specifically approved with respect to brucellosis reactors pursuant to § 78.16(b) of this subchapter.

[28 FR 5961, June 13, 1963, as amended at 29 FR 14490, Oct. 22, 1964; 38 FR 18012, July 6, 1973]

§ 80.2 Notice relating to existence of paratuberculosis.

On June 5, 1952, the Secretary of Agriculture issued a notice that the contagion of paratuberculosis exists in domestic animals in Puerto Rico and in each State of the Continental United States except Arizona, Maine, New Hampshire, Rhode Island, Utah, and Wyoming (17 FR 5260).

§ 80.3 General restrictions.

Domestic animals affected with paratuberculosis may not be moved interstate except in compliance with the regulations in this part.

§ 80.4 Movement of paratuberculosis reactors.

Domestic animals which have reacted to a test recognized by the Secretary of Agriculture for paratuberculosis may be moved interstate under this part for immediate slaughter direct to a slaughtering establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), or a slaughtering establishment specifically approved with respect to brucellosis reactors pursuant to § 78.16(b) of this subchapter, or to a specifically approved stockyard for sale to such a slaughtering establishment, in accordance with the following requirements;

(a) Cattle which have reacted to such a test shall be marked for identification by branding the letter "T" on the left jaw in letters not less than 2 nor more than 3 inches high, and attaching to the left ear a metal tag bearing a serial number and the inscription "U. S. B. A. I. Reacted," or "U.S. Reacted," or a similar State reactor tag. Such a metal tag, affixed to the left ear, shall be sufficient identification for reactors other than cattle.

(b) The reactors shall be accompanied to destination, in accordance with § 80.9, by a certificate issued by a Federal or State inspector or an accredited veterinarian showing: (1) That the animals have reacted to a test recognized by the Secretary of Agriculture for paratuberculosis; (2) the reactor tag number of each animal and the name of the owner of such animal when it was tested for paratuberculosis; (3) that the animals may be moved interstate; (4) the destination to which they are to be moved; and (5) the purpose for which they are moved.

[28 FR 5961, June 13, 1963, as amended at 38 FR 18012, July 6, 1973]

§ 80.5 Reshipment of purebred paratuberculosis reactors.

Purebred animals which have been moved interstate for breeding purposes, and which, subsequent to such movement, have reacted to a test recognized by the Secretary of Agriculture for paratuberculosis, may be reshipped interstate under this part for purposes other than immediate slaughter in accordance with the requirements set forth in paragraphs (a) and (b) of § 80.4 and with the following additional requirements:

(a) The reactors shall be returned to the point of origin, consigned to the original owner.

(b) Test charts for the original test and any subsequent retest, showing that such tests were properly conducted, shall be submitted for examination to the person who issues the certificate required by § 80.4(b).

(c) The reactors shall not be shipped to any State without specific provision by the appropriate livestock sanitary official thereof for the segregation or quarantine of such reactors until their death by slaughter or from natural causes.

(d) The reactors, after return to the point of origin, shall not again be moved interstate except for immediate slaughter in accordance with the provisions of § 80.4.

§ 80.6 Marking of records.

Each transportation agency moving paratuberculosis reactors in the course of their interstate movement shall plainly write or stamp upon the face of each waybill, conductor's manifest, switch order, vehicle interchange record, and similar record, which it prepares in connection with such movement, the words "Paratuberculosis Reactors" and a statement to the effect that the railroad car, boat, truck or vehicle, in which the animals are transported is to be cleaned and disinfected.

§ 80.7 Cleaning and disinfecting vehicles.

(a) Each railroad car, boat, truck, or other vehicle, in which paratuberculosis reactors are transported interstate shall be cleaned and disinfected in accordance with the provisions of §§ 71.6, 71.7, 71.10, and 71.11 of this subchapter: *Provided, however,* That such vehicles may be cleaned and disinfected under the supervision of a Federal or State inspector or an accredited veterinarian: *And provided, further,* That if such supervision or proper cleaning and disinfection facilities are not available at the point where the animals are unloaded, upon permission first secured from the Veterinary Services unit of the Animal and Plant Health Inspection Service, United States Department of Agriculture, the vehicle may be forwarded empty to a point at which such supervision and facilities are available and there be cleaned and disinfected.

(b) Each railroad car, boat, truck, or other vehicle, from which paratuberculosis reactors moved interstate are transferred en route to destination, shall be cleaned and disinfected, by the transportation agency delivering the vehicle to such point of transfer, under the supervision of a Federal or State inspector or an accredited veterinarian, immediately after unloading of the animals and before being moved from such point of transfer, in accordance with the provisions of §§ 71.6, 71.7, 71.10, and 71.11 of this subchapter: *Provided, however,* That if such supervision or proper cleaning and disinfection facilities are not available at such point of transfer, upon having first secured permission from Veterinary Services, the vehicle may be forwarded empty to a point at which such supervision and facilities are available and there be cleaned and disinfected.

(23 Stat. 31, 33; 41 Stat. 699; sec. 2, 65 Stat. 693; sec. 3, 32 Stat. 791, 792; secs. 1, 2, and 4, 33 Stat. 1264; secs. 3, and 11, 76 Stat. 130 and 132; 21 U.S.C. 116, 122-4, 126, 134b, 134f)

[28 FR 5961, June 13, 1963, as amended at 36 FR 24112, Dec. 21, 1971]

§ 80.8 Segregation of paratuberculosis reactors en route interstate.

Paratuberculosis reactors shall not be moved interstate in a railroad car, boat, truck, or other vehicle, containing healthy animals susceptible to paratuberculosis unless all of the animals are for immediate slaughter, or unless the reactors are kept separate from the other animals by a partition securely affixed to the sides of the vehicle.

§ 80.9 Certificates pertaining to movement of animals.

(a) Whenever the regulations in this part require a certificate in connection with the movement of animals and the animals are moved by a transportation agency issuing waybills or other forms of billing covering the movement, the certificate shall be delivered to such transportation agency by the shipper at the time the animals are delivered for shipment; shall become the property of the transportation agency; shall be attached to the billing by the transportation agency; shall accompany such billing to the destination of the animals; and shall be filed with such billing for future reference.

(b) Whenever the regulations in this part require a certificate in connection with the movement of animals and the animals are moved by a transportation agency not issuing waybills or other forms of billing, or moved by any other means, the certificate shall accompany the animals to their destination and be delivered to the consignee, or, in case the consignor and consignee are the same person, to the first person purchasing during or after such movement, or to the person to whom the animals are delivered.

PART 82—EXOTIC NEWCASTLE DISEASE IN ALL BIRDS AND POULTRY; PSITTACOSIS AND ORNITHOSIS IN POULTRY

Sec.
82.1 Definitions.
82.2 General restrictions.
82.3 Imposition and removal of quarantine.
82.4 Restrictions on interstate movement from quarantined areas.
82.5 Cleaning and disinfecting vehicles, premises, and accessories.
82.6 Restrictions on interstate movement of certain Psittacine birds from California.

AUTHORITY: Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132; (21 U.S.C. 111-113, 115, 117, 120, 123-126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141)

SOURCE: 28 FR 5962, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

§ 82.1 Definitions.

As used in connection with this part, the following terms shall have the meaning set forth in this section.

(a)(1) *Exotic Newcastle disease.* The exotic viscerotropic type of Newcastle disease, a contagious, infectious, and communicable disease of poultry.

(i) *Infected group.* A flock or group of birds or poultry, determined by the Director of the Task Force, in his judgment, as being infected with exotic Newcastle disease on the basis of clinical evidence,[1] or epidemiological evidence,[2] or diagnostic tests.[3]

(ii) *Exposed group.* A flock or group of birds or poultry which, through the movement of poultry, birds, personnel, feed or other vectors has been determined by a Federal or State Inspector to have had contact, directly or indirectly, with an exotic Newcastle disease infected flock or group, or to have the potential to spread the disease.

(2) *Psittacosis or ornithosis.* The contagious, infectious, and communicable disease of poultry known as psittacosis or ornithosis.

(b) *State.* Any State, Territory, the District of Columbia, or Puerto Rico.

(c) *Interstate.* From one State into or through any other State.

(d) *Person.* Any person, company, or corporation.

(e) *Moved.* Shipped, transported or otherwise moved, or delivered or received for movement, by any person.

(f) *Veterinary Services.* The Veterinary Services unit of the Animal and Plant Health Inspection Service, United States Department of Agriculture.

(g) *Federal inspector.* An inspector of the Animal and Plant Health Inspection Service, or the Agricultural Marketing Service, United States Department of Agriculture, responsible for the performance of the function involved.

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[1] Clinical evidence—symptoms, post mortem lesions and history of the disease occurrence.

[2] Epidemiological evidence—evaluation of clinical evidence and the degree of risk posed by the potential spread of infection based on population and exposure factors.

[3] Protocol for such diagnostic tests can be found in the "Recommended Uniform Diagnostic Procedures," published by the Committee of the American Association of Veterinary Laboratory Diagnosticians. Copies of the test protocols may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Hyattsville, MD 20782.

(h) *State inspector.* An inspector regularly employed in livestock or poultry sanitary work of a State or a political subdivision thereof, who is authorized by such State or political subdivision to perform the function involved.

(i) *Accredited veterinarian.* A veterinarian specifically approved by the United States Department of Agriculture to perform the function involved.

(j) *Poultry.* Chickens, ducks, geese, swans, turkeys, pigeons, doves, pheasants, grouse, partridges, quail, guinea fowl, pea fowl, of all ages, including eggs for hatching.

(k) *State animal health official.* The animal health official of a State responsible for livestock and poultry disease control and eradication programs.

(l) *Veterinarian in charge.* The veterinary official of Veterinary Services who is delegated by the Deputy Administrator, to supervise and perform the official animal health work of the Animal and Plant Health Inspection Service in the State concerned.

(m) *Director of the task force.* The veterinary official of Veterinary Services who is delegated by the Deputy Administrator to supervise and perform the disease control and eradication work of the task force.

(n) *Deputy Administrator.* The Deputy Administrator, Veterinary Services, or any other official to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(o) *Bird.* Any member of the class of aves other than poultry.

(p) *Task Force.* Special force of Federal and State personnel designated by the Deputy Administrator to control and eradicate exotic diseases from the United States.

(q) *Pet bird.* Any bird which is kept for personal pleasure and is not for sale.

[28 FR 5962, June 13, 1963, as amended at 29 FR 14490, Oct. 22, 1964; 36 FR 25218, Dec. 30, 1971; 45 FR 67054, Oct. 9, 1980; 47 FR 11245, Mar. 16, 1982]

§ 82.2 General restrictions.

(a) Notice is hereby given that poultry, psittacine and mynah birds, and birds of all other species are susceptible to Exotic Newcastle Disease and that the Administrator has determined that, in order to prevent the interstate dissemination of such disease to poultry and to effectuate the eradication of such disease, it is necessary to make all of the provisions of this Part 82 relating to poultry applicable to psittacine and mynah birds and birds of all other species, of all ages, which are under any form of confinement, including eggs from such birds. Accordingly, the provisions of this Part 82 shall be applicable in relation to such birds in the same manner, and to the same extent as such provisions are applicable in relation to poultry.

(b) Poultry affected with psittacosis or ornithosis, and carcasses, parts and offal of such poultry, shall not be moved interstate for any purpose.

[28 FR 5962, June 13, 1963, as amended at 36 FR 25218, Dec. 30, 1971; 37 FR 135, Jan. 6, 1972; 45 FR 67054, Oct. 9, 1980]

§ 82.3 Imposition and removal of quarantine.

(a) *Infected group.* (1) Any premises on which an infected group exists shall be quarantined.

(2) *Removal of quarantine.* In order for the premises to be released from a quarantine imposed under paragraph (a)(1) of this section, the following conditions must be satisfied:

(i) All poultry or birds on the quarantined premises must be destroyed, buried, incinerated, or otherwise properly disposed of as the Deputy Administrator may direct to prevent the spread of communicable diseases of poultry. When an infected group includes endangered species of birds, as determined by the U.S. Department of the Interior, the U.S. Department of the Interior will be consulted on final disposition.

(ii) Vehicles, premises and accessories determined by Federal or State inspectors to have come in contact with an infected group shall be cleaned and disinfected in accordance with § 71.7 of this subpart. Any such items which are not suitable for disinfection shall be destroyed.

(3) Repopulation of the premises with birds or poultry shall not occur until after the premises and surrounding areas have been evaluated by the Veterinarian in Charge or State animal health official or Director of the task force and is found to be free from the disease.

(b) *Exposed group.* (1) Any premises on which an exposed group exists shall be quarantined.

(2) Should any bird in an exposed group be determined by the Director of the Task Force, in his judgment based upon clinical[1] or epidemiological evidence[2] or diagnostic tests[3] to be infected with exotic Newcastle disease, that group shall be declared an infected group and shall thereafter be handled as required for an infected group in this part.

(3) For premises to be released from quarantine imposed under paragraph (b)(1) of this section, the exposed group must be determined by the Director of the Task Force, in his judgment, through clinical[1] and epidemiological evidence[2] and diagnostic tests[3] to be free from exotic Newcastle disease; *Provided,* That the Director of the Task Force may determine diagnostic tests are not necessary if sufficient clinical and epidemiological evidence exists to make such a determination of freedom from exotic Newcastle disease.

(c) Notice is hereby given that the contagion or vectors of exotic Newcastle disease, a contagious, infectious and communicable disease, exist in the following areas or that animals and/or live poultry affected with or exposed to exotic Newcastle disease exist in the following areas, and, therefore, the following areas are hereby quarantined because of said disease:

(1) *New York.*

(2) *California.*

(3) *California.* (i) [Reserved]

[36 FR 25218, Dec. 30, 1971]

EDITORIAL NOTE: The quarantined areas in paragraph (c) of § 82.3 are not carried in the Code of Federal Regulations. For Federal Register citations affecting § 82.3, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 82.4 Restrictions on interstate movement from quarantined areas.

No poultry or birds, eggs, poultry carcasses, or parts thereof, or manure from poultry or birds, or litter, coops, containers, or other accessories used in the handling of poultry or birds in any quarantined area shall be moved interstate from such area, except as provided in this section:

(a) Live poultry may be moved interstate from such areas to a federally inspected slaughtering establishment for immediate slaughter upon prior approval by the Deputy Administrator, Veterinary Services, when he determines in the specific case that such movement will not involve a risk of interstate spread of exotic Newcastle disease.[4]

(b) Table eggs and eggs for processing may be moved interstate from quarantined areas if washed and sanitized and moved in new flats and cases or in plastic flats and cases which have been washed and sanitized since last use.

(c) A lot consisting of no more than two psittacine or mynah birds or birds of any other species, which are not known to be affected with or exposed to any communicable disease of poultry, which are caged and are personal pets may be moved interstate by the owner thereof from any quarantined area, if (1) prior to such movement, the owner of such birds signs and furnishes to a Federal inspector in the State of origin of the movement[5] a notarized declaration under oath or affirmation stating that the birds have been in his possession for a minimum of 90 days preceding the interstate movement, that such birds have not shown any signs of illness during that period, and that such birds have not been in contact with poultry or other birds (including association with any other birds at exhibitions or in aviaries) in the quarantined area during that period; (2) prior to such movement, the owner signs an agreement[6] on a form obtainable from a Federal inspector in the State of origin of the movement[5] stating that the birds will be maintained in his personal possession separate and apart from all poultry or other birds, in a place approved by the Deputy Administrator, at destination, for a minimum of 30 days following such interstate movement and until released by a Federal or State inspector of the State of destination;[6] that the birds will be made available for health inspection by a Federal or State inspector, or both, upon request until so released, and that Federal or State officials of the State of destination[6] will be immediately notified if any signs of disease are noted in any of the birds or any of the birds die during that period; and (3) there is compliance with the terms of such agreement.

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[1] Clinical evidence—symptoms, post mortem lesions and history of the disease occurrence.

[2] Epidemiological evidence—evaluation of clinical evidence and the degree of risk posed by the potential spread of infection based on population and exposure factors.

[3] Protocol for such diagnostic tests can be found in the "Recommended Uniform Diagnostic Procedures," published by the Committee of the American Association of Veterinary Laboratory Diagnosticians. Copies of the test protocols may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Hyattsville, MD 20782.

[4] Requests for Deputy Administrator's approval to move live poultry from quarantined areas should be made through the Veterinarian in Charge, Veterinary Services, Animal and Plant Health Inspection Service, for the State in which the areas are quarantined.

(d) Poultry or bird coops made of hard plastic or metal may be moved interstate from quarantined areas if they have been cleaned and disinfected with a permitted disinfectant specified in §§ 71.10 and 71.11 of this subchapter under the supervision of a Federal or State inspector.

(e) Manure from poultry or birds may be moved interstate from a quarantined area only if:

(1) The manure originates from poultry not known by a State or Federal inspector to be affected with exotic Newcastle disease, and is not moved onto or through any premises known by a State or Federal inspector to be affected with exotic Newcastle disease;

(2) The manure has been heated throughout to a temperature of not less than 175°F. (79.4°C.);

(3) The heated manure is sealed in unused, airtight, containers immediately after heating and prior to its movement from the facility in which it is heated; and

(4) Prior to the movement from the facility in which the manure is heated the shipper furnishes to a Federal inspector in the State of origin of the movement[5] a notorized declaration, under oath or affirmation, stating the location of the poultry from which the manure originated and the name and address of the owner of such poultry; the quantity of manure to be moved; the destination of the shipment; and that all of the provisions of paragraphs (e) (1), (2), and (3) of this section have been complied with.

(f) *Other movements.* The Deputy Administrator may upon request in specific cases permit the movement, not otherwise provided for in this section, of poultry not known to be affected with exotic Newcastle disease, under such conditions as he may prescribe in each case to prevent the spread of such disease. The Deputy Administrator will promptly notify the appropriate livestock sanitary officials of the States involved of any such action.

[36 FR 25218, Dec. 30, 1971, as amended at 37 FR 3050, Feb. 11, 1972; 37 FR 28710, Dec. 29, 1972; 38 FR 9088, Apr. 10, 1973; 44 FR 19373, Apr. 3, 1979; 45 FR 67055, Oct. 9, 1980]

§ 82.5 Cleaning and disinfecting vehicles, premises, and accessories.

(a) Railroad cars, boats, trucks, and other vehicles, and yards and other premises, which have contained poultry or birds affected with Exotic Newcastle disease or psittacosis or ornithosis shall be cleaned and disinfected in accordance with the provisions of §§ 71.4, 71.6, 71.7, 71.10, and 71.11 of this subchapter: *Provided, however,* That such vehicles, and yards and other premises, may be cleaned and disinfected under the supervision of a Federal inspector, a State inspector, or an accredited veterinarian: *And provided, further,* That if such supervision or proper cleaning and disinfection facilities are not available at the point where the poultry or birds are unloaded, upon permission first received from Veterinary Services, such a vehicle may be forwarded to a point at which such supervision and facilities are available and there be cleaned and disinfected.

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[5] Information as to the location of such inspectors can be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

[6] Owners will be provided a copy of the agreement containing the name and address of the appropriate Federal and State officials of the State of destination. Animal Health officials in States of destination of pet birds to be moved from a quarantined area will be immediately notified by the Federal official in the originating State when such movement into the particular State is made under a declaration furnished to such Federal official.

(b) Coops, containers, troughs, and other accessories used in the handling of an interstate movement of poultry affected with psittacosis or ornithosis shall be cleaned and disinfected as soon as possible thereafter and before such accessories are moved from the point of unloading. Such cleaning and disinfecting shall be done under the supervision of a Federal inspector, a State inspector, or an accredited veterinarian, with a permitted disinfectant specified in §§ 71.10 and 71.11 of this subchapter. If such supervision or proper cleaning and disinfection facilities are not available at the point where the poultry is unloaded, upon permission first received from the Veterinary Services, such an accessory may be forwarded to a point at which such supervision and facilities are available and there be cleaned and disinfected.

(c) Coops, containers, troughs, and other accessories used in the handling of an intrastate movement of poultry affected with psittacosis or ornithosis shall not be moved interstate until such accessories have been cleaned and disinfected under the supervision of a Federal inspector, a State inspector, or an accredited veterinarian, with a permitted disinfectant specified in §§ 71.10 and 71.11 of this subchapter.

[28 FR 5962, June 13, 1963, as amended at 36 FR 24112, Dec. 21, 1971. Redesignated and amended at 36 FR 25218, Dec. 30, 1971; 45 FR 67055, Oct. 9, 1980]

§ 82.6 Restrictions on interstate movement of certain psittacine birds from California.

(a) No person shall move interstate from California a psittacine bird, other than a budgerigar, lovebird, or cockatiel, and other than each pet bird in a lot of two are fewer pet birds accompanied by the owner, unless:

(1) The bird is banded with a legband issued pursuant to § 92.11(e) of this chapter or issued pursuant to paragraph (b) of this section,[7] and

(2) The bird is accompanied by a waybill, an invoice, or a similar document, signed and dated by a federal inspector,[7] stating:

(i) The point in California from which the bird is intended to be moved interstate,

(ii) The destination of the bird,

(iii) The species and common names, and number of birds covered by the document,

(iv) The name and address of the owner or shipper of the bird, and

(v) The identifying legband number on the bird.

(b) For compliance with provisions of paragraph (a) of this section, a legband shall be issued by a federal inspector for a psittacine bird, or a document shall be signed and dated by a federal inspector for the interstate movement of a psittacine bird from California, if, based on the federal inspector's examination of the bird, there is no evidence that the bird is exposed to or infected with exotic Newcastle disease, and if the inspector determines that there is no substantial evidence that the bird was imported contrary to the provisions of Part 92 of this chapter. Such a legband may be denied, or the signature and date may be withheld, upon a finding that the bird is exposed to or infected with exotic Newcastle disease or that there is substantial evidence to establish that the bird was imported contrary to the provisions of Part 92 of this chapter. The reasons for the denial or withholding shall be confirmed in writing as promptly as circumstances allow. Any person who has been denied the issuance of a legband or had a signature and date withheld may appeal the decision in writing to the Deputy Administrator within twenty days after receiving a written confirmation of such action. The appeal shall state all of the facts and reasons upon which the person relies to show that the legband was wrongfully denied or that the signature and date were wrongfully withheld. The Deputy Administrator shall grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict.

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[7] Information about obtaining legbands, or signatures and dates is available from Federal Veterinary Services personnel. Local offices are listed in the telephone directories.

(c) The legbands issued pursuant to paragraph (b) of this section and the services performed pursuant to paragraph (b) of this section by federal inspectors during regularly assigned hours of duty shall be furnished without cost.

[47 FR 11245, Mar. 16, 1982]

EDITORIAL NOTE: At 47 FR 16773, Apr. 20, 1982, § 82.6 was suspended until further notice.

PART 85—PSEUDORABIES

Sec.
85.1 Definitions.
85.2 Notice relating to the existence of the contagion of pseudorabies.
85.3 General restriction.
85.4 Interstate movement of livestock.
85.5 Interstate movement of infected swine or exposed swine.
85.6 Interstate movement of pseudorabies vaccinate swine not known to be infected with or exposed to pseudorabies.
85.7 Interstate movement of swine not vaccinated for pseudorabies and not known to be infected with or exposed to pseudorabies.
85.8 Other interstate movements.
85.9 Interstate movement of swine semen and swine embryos for insemination of or implantation into swine.
85.10 Permits and certificates.
85.11 Maintenance of records.
85.12 Cleaning and disinfecting means of conveyance.
85.13 Cleaning and disinfecting livestock markets and other facilities.

AUTHORITY: 21 U.S.C. 111, 112, 113, 115, 117, 120, 121, 123-126, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 44 FR 10309, Feb. 16, 1979, unless otherwise noted.

§ 85.1 Definitions.

For purposes of this part, the following terms mean:

Accredited veterinarian. A veterinarian approved by the Deputy Administrator in accordance with Part 161 of this Title to perform functions specified in Part 11 of Subchapter A, and Subchapters B, C, and D of this Chapter, and to perform functions required by cooperative State-Federal disease control and eradication programs.

Administrator. The Administrator of the Animal and Plant Health Inspection Service, United States Department of Agriculture, or any other official of the Service to whom authority has been delegated or may be delegated to act in his stead.

Approved livestock market. A stockyard, livestock market, buying station, concentration point or any other premises under State or Federal veterinary supervision where swine are assembled for sale or sale purposes, and which has been approved by the Deputy Administrator under § 76.18 (9 CFR 76.18).[8] [9]

Certificate. An official document issued for and prior to the interstate movement of swine not known to be infected with, exposed to or vaccinated for pseudorabies under this part by a Veterinary Services representative, a State representative, or an accredited veterinarian which states: (1) The number and description of the swine to be moved; (2) that the swine to be moved are not known to be infected with or exposed to pseudorabies and are not pseudorabies vaccinates; (3) the purpose for which the swine are to be moved; (4) the points of origin and destination; (5) the consignor and consignee; and (6) and additional information required by this part.

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[8] Notices containing lists of such approved livestock markets are published in the FEDERAL REGISTER. Information concerning livestock markets can be obtained from the Veterinarian in Charge, Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture for the State in question.

[9] Before the Deputy Administrator withdraws approval of any livestock market, the owner of such livestock market shall be given notice by the Deputy Administrator of the proposed withdrawal of approval and the reasons therefor and such owner shall have an opportunity to present his views thereon. In those instances where there are conflicts as to the facts, a hearing shall be held to resolve such conflicts.

Common ground. The ground, areas, buildings or equipment communally shared by any specific group or groups of livestock.

Contact. Direct access to other swine, their excrement, or discharges; or sharing a building with a common ventilation system with other swine, or being within ten feet of other swine if not sharing a building with a common ventilation system.

Deputy Administrator. The Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, or any other Veterinary Services official to whom authority has been delegated or may be delegated to act in his stead.

Exposed livestock. Any livestock that has been in contact with an animal infected with pseudorabies, including all livestock in a known infected herd; except that livestock, other than swine, that have not been exposed to a clinical case of the disease for a period of 10 consecutive days shall no longer be considered to be exposed livestock.

Exposed swine. Any swine that has been in contact with an animal infected with pseudorabies, including all swine in a known infected herd.

Farm of origin. A farm where the swine were born, or on which they have resided for at least 90 consecutive days immediately prior to the interstate shipment.

Feedlot. A premises where swine are fed physically separated from swine kept for breeding or other purposes and from which such swine are moved directly to a recognized slaughtering establishment or directly through one or more slaughter markets and then directly to a recognized slaughtering establishment, quarantined herd, or quarantined feedlot.

Herd. Any group of livestock maintained on common ground for any purpose, or two or more groups of livestock under common ownership or supervision, geographically separated, but which have an interchange or movement of animals without regard to whether the animals are infected with or exposed to pseudorabies.

Infected livestock. Any livestock determined to be infected with pseudorabies by an official pseudorabies test, or diagnosed by a veterinarian as having pseudorabies.

Interstate. From any State into or through any other State.

Isolation. Separation of swine by a physical barrier in such a manner that other swine do not have access to the isolated swine's body, excrement, or discharges; not allowing the isolated swine to share a building with a common ventilation system with other swine; and not allowing the isolated swine to be within ten feet of other swine if not sharing a building with a common ventilation system.

Known infected herd. Any herd in which any livestock has been determined to be infected with pseudorabies by an official pseudorabies test or diagnosed by a veterinarian as having pseudorabies.

(1) A herd of livestock, other than swine, shall no longer be classified as a known infected herd after 10 days since the last clinical case of pseudorabies in the herd.

(2) A herd of swine which has been released from pseudorabies quarantine in accordance with the following provisions shall no longer be classified as a known infected herd if:

(i) All swine positive to an official pseudorabies test have been removed from the premises; all swine which remain in the herd, except swine nursing from their mothers, are subjected to an official pseudorabies serologic test and found negative 30 days or more after removal of swine positive to an official pseudorabies test; and no livestock on the permises have shown clinical signs of pseudorabies after removal of the postive swine; or

(ii) All swine have been depopulated for 30 days and the herd premises have been cleaned and disinfected in accordance with § 85.13; or

(iii) In a herd of swine in which swine are positive to an official pseudorabies serologic test but no swine are postive at titers greater than 1:8, all titered swine are subjected to another official pseudorabies serologic test and found negative; and all other swine in the herd which an epidemiologist, approved by the State animal health official and the Veterinarian in Charge, requires to be subjected to an official pseudorabies serologic test are tested and found negative.[1]

Livestock. Swine, cattle, sheep or goats.

Moved. Shipped, transported, or otherwise moved, or delivered or received for movement by land, water, or air.

Official pseudorabies serologic test. An official pseudorabies test, as defined in paragraph (q) of this section, conducted on swine serum to detect the presence or absence of pseudorabies antibodies.

Official pseudorabies test. Any test for the diagnosis of pseudorabies approved by the Deputy Administrator conducted in a laboratory approved by the Deputy Administrator as listed in a Veterinary Services Notice listing such laboratories.[2] The following tests for the diagnosis of pseudorabies have been approved by the Deputy Administrator: 1. Microtitration Serum-Virus Neutralization Test; 2. Virus Isolation and Identification Test; 3. Fluorescent Antibody Tissue Section Test; and 4. Enzyme-Linked Immunosorbent Assay (ELISA) Test.[3] State, Federal, and University laboratories will be approved by the Deputy Administrator following the determination by him that the laboratory: (1) Has personnel trained at the Veterinary Services Diagnostic Laboratory, Ames, Iowa, assigned to supervise the test, (2) follows standard test protocol, (3) meets check test proficiency requirements, and (4) will report all test results to State and Federal animal health officials.[4]

Official pseudorabies vaccine. Any pseudorabies virus vaccine produced under license from the Secretary of Agriculture under the Virus, Serum and Toxin Act of March 4, 1913, and any legislation amendatory thereof (21 U.S.C. 151 *et seq.*).

Official vaccinate. Any swine which have been: (1) Vaccinated with an official pseudorabies vaccine by an accredited veterinarian or a State or Federal veterinarian in accordance with recommendations on the vaccine label and the laws and regulations of the State in which the swine are vaccinated; (2) identified by a numbered pink eartag approved by the State in which such swine are vaccinated; [7] and (3) reported as official vaccinates at the time of vaccination to the State animal health official.

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[1] The epidemiologist shall consider the following epidemiologic evidence to determine which swine in the herd, in addition to the titered swine, must be subjected to an official pseudorbies serologic test and found negative: (a) the percentage and number of titered swine in the herd; (b) the number of titered swine as compared to the number of swine tested; (c) the extent of the contact of members of the herd with the titered swine; (d) the prevalence of pseudorabies in the area; (e) the herd management practices; and (f) any other reliable epidemiologic evidence.

[2] Notices containing lists of laboratories approved for the purposes of the regulations in this part are published in the FEDERAL REGISTER Notices Section. The lists are also available upon request from Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

[3] Copies of the test protocols (Recommended Minimum Standards for Diagnostic Tests Employed in the Diagnosis of Pseudorabies (Aujeszky's Disease)) published as a Veterinary Services Notice, May 17, 1978, are available upon request from Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

[4] Before the Deputy Administrator withdraws the approval of any laboratory, the Director of such laboratory shall be given a notice by the Deputy Administrator of the proposed disapproval and the reasons therefore and such Director shall have an opportunity to present his views thereon. In those instances where there are conflicts as to the facts, a hearing shall be held to resolve such conflicts.

[7] The numbered pink eartags are available commercially. Should any problem arise regarding the availability of such eartags, contact the appropriate State animal health official.

Owner-shipper statement. A statement signed by the owner or shipper of swine which states: (1) The number of swine to be moved; (2) the points of origin and destination; (3) the consignor and consignee; and (4) any additional information required by this part.

Permit. An official document issued for and prior to the interstate movement of pseudorabies infected, exposed or vaccinated swine under this part by a Veterinary Services representative, State representative, or an accredited veterinarian which states: (1) The number of swine to be moved; (2) the purpose for which the swine are to be moved; (3) the points of origin and destination; (4) the consignor and the consignee; and (5) any additional information required by this part.

Pseudorabies. The contagious, infectious, and communicable disease of livestock and other animals also known as Aujeszky's disease, mad itch, or infectious bulbar paralysis.

Pseudorabies controlled vaccinated herd. (1) Pseudorabies controlled vaccinated herd status is attained by subjecting all swine over 6 months of age to an official pseudorabies serologic test and finding all swine so tested negative. The herd must not have been a known infected herd within the past 30 days. Any swine in the herd over 6 months of age may be vaccinated for pseudorabies within 15 days after being subjected to an official pseudorabies serologic test and found negative.[1]

(2) If on the qualifying official pseudorabies serologic test or any subsequent official pseudorabies test, any swine so tested are positive, pseudorabies controlled vaccinated herd status is attained or regained by: removing all positive swine; cleaning and disinfecting the herd premises in accordance with § 85.13; subjecting all swine in the herd, except swine nursing from their mothers, to an official pseudorabies serologic test 30 days or more after removal of the positive swine and finding all swine so tested negative; and, after an interval of 30 to 60 days after the first such negative official pseudorabies serologic herd test, subjecting all swine in the herd over 6 months of age to another official pseudorabies serologic test and finding all swine so tested negative.

(3)(i) Pseudorabies controlled vaccinated herd status is maintained by: subjecting 25 percent of all the offspring to an official pseudorabies serologic test when they are between 16 and 20 weeks of age and finding all swine so tested negative, or by leaving 10 percent of the swine over 6 months of age in the herd unvaccinated and subjecting all such unvaccinated swine to an official pseudorabies serologic test every 80-105 days and finding all swine so tested negative.

(ii) Any swine in the herd over 6 months of age may be vaccinated for pseudorabies within 15 days after being subjected to an official pseudorabies serologic test and found negative; *Provided that,* if pseudorabies controlled vaccinated herd status is to be maintained by testing unvaccinated swine over 6 months of age, at least 10 percent of the swine in the herd over 6 months of age shall remain unvaccinated.

(iii) All swine intended to be added to a pseudorabies controlled vaccinated herd shall be isolated until the swine have been found negative to an official pseudorabies serologic test conducted 30 days or more after the swine have been placed in isolation. Not more than 90 percent of the swine over 6 months of age added to the herd may be vaccinated for pseudorabies. All additions to the herd which are to be vaccinated for pseudorabies shall be vaccinated within 15 days after being subjected to such official pseudorabies serologic test. All additions to the herd shall be added to the herd within 30 days after such official pseudorabies serologic test.

(iv) Swine which have not been vaccinated for pseudorabies and which are to be tested to maintain pseudorabies controlled vaccinated herd status shall be maintained in the herd so that the pseudorabies vaccinates can physically touch nonvaccinates or so that the pseudorabies vaccinates are within 10 feet of nonvaccinates while sharing a direct common ventilation system with such nonvaccinates.

Pseudorabies vaccinate. Any swine that have been vaccinated with any product containing antigens for pseudorabies.

Qualified pseudorabies negative herd. (1) Qualified pseudorabies negative herd status is attained by subjecting all swine over 6 months of age to an official pseudorabies serologic test and finding all swine so tested negative. The herd must not have been a known infected herd within the past 30 days. A minimum of 90 percent of the swine in the herd must have been on the premises and a part of the herd for at least 90 days prior to the qualifying official pseudorabies serologic test or have entered directly from another qualified pseudorabies negative herd.

(2)(i) If on a qualifying official pseudorabies serologic test or any subsequent official pseudorabies test, any swine so tested are positive, qualified pseudorabies negative herd status is attained or regained by: removing all positive swine and cleaning and disinfecting the herd premises in accordance with § 85.13; subjecting all swine in the herd, except swine nursing from their mothers, to an official pseudorabies serologic test 30 days or more after removal of the positive swine and finding all swine so tested negative; and, after an interval of 30 to 60 days after the first such negative official pseudorabies serologic herd test, subjecting all swine in the herd over 6 months of age to another official pseudorabies serologic test and finding all swine so tested negative; or

(ii) If on any qualifying official pseudorabies serologic test or any subsequent official pseudorabies serologic test, any swine so tested are positive, but no swine are positive at titers greater than 1:8, qualified pseudorabies negative herd status is attained or regained by: Subjecting all titered swine and all other swine required to be tested by an epidemiologist, approved by the State animal health official and the Veterinarian in Charge, to an official pseudorabies serologic test and finding all such swine negative.[1]

(3) Qualified pseudorabies negative herd status is maintained by subjecting all swine over 6 months of age in the herd to an official pseudorabies serologic test at least once each year (this must be accomplished by testing 25 percent of swine over 6 months of age every 80-105 days and finding all swine so tested negative, or by testing 10 percent of the swine over 6 months of age each month and finding all swine so tested negative; no swine shall be tested twice in 1 year to comply with the 25 percent requirement or twice in 10 months to comply with the 10 percent requirement). All swine intended to be added to a qualified pseudorabies negative herd shall be isolated until the swine have been found negative to two official pseudorabies serologic tests, one conducted 30 days or more after the swine have been placed in isolation, the second test being conducted 30 days or more after the first test; except (i) swine intended to be added to a qualified pseudorabies negative herd directly from another qualified pseudorabies negative herd may be added without isolation or testing; (ii) swine intended to be added to a qualified pseudorabies negative herd from another qualified pseudorabies negative herd, but with interim contact with swine other than those from a single qualified pseudorabies negative herd, shall be isolated until the swine have been found negative to an official pseudorabies serologic test, conducted 30 days or more after the swine have been placed in isolation; (iii) swine returned to the herd after contact with swine other than those from a single qualified pseudorabies negative herd shall be isolated until the swine have been found negative to an official pseudorabies serologic test conducted 30 days or more after the swine have been placed in isolation.

Quarantined feedlot. A premises where pseudorabies infected or exposed swine are fed under the supervision and control of the State animal health official, and from which such swine are moved directly to a recognized slaughtering establishment or directly through one or more slaughter markets and then directly to a recognized slaughtering establishment in accordance with the provisions of this part.

Quarantined herd. A herd in which pseudorabies infected or exposed swine are bred, reared, and fed under the supervision and control of the State animal health official, and from which such swine are moved interstate directly to a recognized slaughtering establishment or directly through one or more slaughter markets and then directly to a recognized slaughtering establishment, or from which exposed officially vaccinated swine which were negative to an official pseudorabies serologic test may be moved only to a quarantined herd or quarantined feedlot.

Recognized slaughtering establishment. A slaughtering establishment operated under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or a State inspected slaughtering establishment.

Slaughter market. A livestock market approved in accordance with § 76.18 (9 CFR 76.18), at which swine for sale and shipment for slaughter are handled only on days when no swine are handled for sale and shipment for feeding or breeding purposes unless facilities are provided to keep slaughter swine physically separated from feeder and breeder swine, and feeder and breeder swine use no facilities previously used by slaughter swine on the day these classes of swine are at the market. The facilities used by slaughter swine shall be cleaned and disinfected in accordance with the requirements of this part before being used for feeding or breeding swine.[5] [6]

State. Any State or Territory of the United States, the District of Columbia, Puerto Rico, Guam or the Northern Mariana Islands.

State animal health official. The State animal health official who is responsible for the livestock and poultry disease control and eradication programs in the official's State or his designated representative.

State representative. A person regularly employed in animal health work of a State and who is authorized by such State to perform the function involved under a Cooperative Agreement with the United States Department of Agriculture.

Swine not known to be infected with or exposed to pseudorabies. Any swine from a herd of swine in which no animal has been classified as a reactor to an official pseudorabies test, or has been diagnosed as having pseudorabies or suspected of having pseudorabies by a veterinarian; or any swine from a herd of swine which has been released from quarantine or has met the requirements of release from quarantine in accordance with the definition of known infected herd in § 85.1.

Veterinarian in charge. The veterinary official of Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, who is assigned by the Deputy Administrator to supervise and perform official animal health work of the Animal and Plant Health Inspection Service in the State concerned.

Veterinary Services. Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture.

Veterinary Services representative. A person employed by Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, who is authorized to perform the function involved.

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[44 FR 10309, Feb. 16, 1979; 44 FR 12159, Mar. 6, 1979, as amended at 48 FR 57472, Dec. 30, 1983; 50 FR 42145, Oct. 18, 1985; 50 FR 47350, Nov. 15, 1985]

§ 85.2 Notice relating to the existence of the contagion of pseudorabies.

Notice is hereby given that there is reason to believe that the contagion of pseudorabies may exist in each State and that to prevent the spread and dissemination of the contagion thereof, and to protect the livestock of the United States, the regulations in this part are promulgated.

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[5] Notices containing lists of slaughter markets approved for the purposes of the regulations in this part are published in the FEDERAL REGISTER. Information concerning slaughter markets can be obtained from the Veterinarian in Charge, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, for the State in question.

[6] Before the Deputy Administrator withdraws approval of any slaughter market, the owner of such slaughter market shall be given notice by the Deputy Administrator of the proposed withdrawal of approval and the reasons therefore and such owner shall have an opportunity to present his views thereon. In those instances where there are conflicts as to the facts, a hearing shall be held to resolve such conflicts.

§ 85.3 General restriction.

Livestock shall not be moved interstate except in compliance with the regulations in this part.

§ 85.4 Interstate movement of livestock.

(a) Livestock showing clinical evidence of pseudorabies shall not be moved interstate.

(b) Livestock that have been exposed to an animal showing clinical evidence of pseudorabies shall not be moved interstate within 10 days of such exposure.

(c) Except as provided in paragraphs (a) and (b) of this section, livestock other than swine may be moved interstate without restriction under this part.

(d) Except as provided in paragraphs (a) and (b) of this section, swine, swine semen, and swine embryos shall be moved interstate only in compliance with the regulations in this part.

[44 FR 10309, Feb. 16, 1979, as amended at 50 FR 47352, Nov. 15, 1985]

§ 85.5 Interstate movement of infected swine or exposed swine.

Infected swine or exposed swine, other than swine described in § 85.4 (a) or (b), shall only be moved interstate in accordance with the following provisions:

(a) *Movement of infected or exposed swine for slaughter.* Infected or exposed swine shall be moved interstate for slaughter only if:

(1) The swine are moved directly to a recognized slaughtering establishment or directly through one or more slaughter markets and then directly to a recognized slaughtering establishment;

(2) The swine are accompanied by a permit or owner-shipper statement and such permit or owner-shipper statement is delivered to the consignee;

(3) The permit, in addition to the information in § 85.1, or the owner-shipper statement, in addition to the information in § 85.1, lists the identification tag, tattoo, earnotch recognized by a breed association, or similar identification of each swine being moved; *except* if the swine are moved interstate and the indentity of the farm of origin of each swine is maintained, the permit or the owner-shipper statement need not list the individual identification required by this paragraph, if such swine are identified to the farm of orgin at the recognized slaughtering establishment or the first slaughter market; and

(4) The swine are moved to destination in one continuous movement without unloading enroute.

(b) *Movement of exposed swine to a quarantined herd or a quarantined feedlot.* Exposed swine shall be moved interstate directly to a quarantined herd or quarantined feedlot only if:

(1) The swine are negative to an official pseudorabies serologic test 21 days or more after last being exposed to any livestock showing clinical evidence of pseudorabies;

(2) The swine are officially vaccinated for pseudorabies within 15 days after the negative test;

(3) The swine are moved interstate within 30 days after the negative test;

(4) The swine are accompanied by a permit and such permit is delivered to the consignee; and

(5) The permit, in addition to the information described in § 85.1, states: (i) The present pseudorabies quarantine status of the farm of origin; (ii) the identification tag, tattoo, earnotch recognized by a breed association, or similar identification of each animal being moved; (iii) the date of the official pseudorabies serologic test and the name of the laboratory where the test was conducted; (iv) the date of the official vaccination for pseudorabies; and (v) that approval for the interstate movement has been issued by the State animal health official of the State of destination prior to the interstate movement of the swine.

(Approved by the Office of Management and Budget under control number 0579-0070)

[44 FR 10309, Feb. 16, 1979, as amended at 48 FR 57472, Dec. 30, 1983; 50 FR 47352, Nov. 15, 1985]

§ 85.6 Interstate movement of pseudorabies vaccinate swine not known to be infected with or exposed to pseudorabies.

Pseudorabies vaccinate swine not known to be infected with or exposed to pseudorabies shall only be moved interstate in accordance with the following provisions:

(a) *Movement of pseudorabies vaccinate swine for slaughter.* Pseudorabies vaccinate swine not known to be infected with or exposed to pseudorabies shall be moved interstate for slaughter only if:

(1) The swine are moved directly to a recognized slaughtering establishment or directly through one or more slaughter markets and then directly to a recognized slaughtering establishment;

(2) The swine are accompanied by a permit or owner-shipper statement and such permit or owner-shipper statement is delivered to the consignee; and

(3) The swine are moved to destination in one continuous movement without unloading enroute.

(b) *Movement of pseudorabies vaccinate swine to a quarantined herd or quarantined feedlot.* Pseudorabies vaccinate swine not known to be infected with or exposed to pseudorabies shall be moved interstate directly to a quarantined herd or quarantined feedlot only if:

(1) The swine are accompanied by a permit and such permit is delivered to the consignee; and

(2) The permit in addition to information described in § 85.1 states: (i) The pseudorabies status of the herd; (ii) the identification tag, tattoo, earnotch recognized by a breed association, or similar identification of each animal being moved; (iii) the date of the vaccination for pseudorabies; and (iv) that approval for the interstate movement has been issued by the State animal health official of the State of destination prior to the interstate movement of the swine.

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[44 FR 10309, Feb. 16, 1979, as amended at 48 FR 57472, Dec. 30, 1983; 50 FR 47352, Nov. 15, 1985]

§ 85.7 Interstate movement of swine not vaccinated for pseudorabies and not known to be infected with or exposed to pseudorabies.

Swine not vaccinated for/pseudorabies and not known to be infected with or exposed to pseudorabies shall only be moved interstate in accordance with the following provisions:

(a) *Movement for slaughter.* Swine not vaccinated for pseudorabies and not known to be infected with or exposed to pseudorabies may be moved interstate for slaughter without further restriction under this part directly to a recognized slaughtering establishment or directly through one or more slaughter markets and then directly to a recognized slaughtering establishment.

(b) *Movement to a feedlot, quarantined feedlot, quarantined herd, or approved livestock market.* Swine not vaccinated for pseudorabies and not known to be infected with or exposed to pseudorabies may be moved interstate only if:

(1) The swine are moved from a qualified pseudorabies negative herd directly to a feedlot, quarantined feedlot, quarantined herd, or approved livestock market; or

(2) The swine are moved directly to a feedlot, quarantined feedlot, quarantined herd, or to an approved livestock market for subsequent movement to a feedlot or quarantined feedlot, quarantined herd in accordance with paragraph (c) of this section; or

(3) The swine are moved from a State which requires the State animal health official of that State to be immediately notified of any suspected or confirmed case of pseudorabies in that State and which requires that exposed or infected livestock be quarantined, such quarantine to be released only after having met quarantine release standards no less restrictive than those in the definition of known infected herd in § 85.1, and

(i) The swine are accompanied by an owner-shipper statement and are moved from a farm of origin directly to an approved livestock market; and

(A) The owner-shipper statement is delivered to the consignee, and

(B) The swine are identified at the approved livestock market to the farm of origin by an identification tag, or

(ii) The swine are accompanied by a certificate and such certificate is delivered to the consignee; the certificate, in addition to the information in § 85.1, states the identification of the farm of origin of each swine being moved by an earnotch recognized by a breed associated, identification tag, tattoo, or similar identification, and approval for the interstate movement has been issued by the State animal health official of the State of destination prior to the interstate movement of the swine, and

(A) The swine are move directly to a feedlot, quarantined feedlot, quarantined herd or approved livestock market from a farm of origin; or

(B) The swine are moved directly to a feedlot, quarantined feedlot, quarantined herd or approved livestock market from an approved livestock market which received the swine directly from a farm of origin, or

(C) The swine are moved directly to a feedlot, quarantined feedlot, or quarantined herd from an approved livestock market, which received the swine from another approved livestock market, which received the swine directly from a farm of origin.

(c) *General movements.* Swine not vaccinated for pseudorabies and not known to be infected with or exposed to pseudorabies may be moved interstate only if:

(1) The swine are accompained by a certificate and such certificate is delivered to the consignee; and

(2) The certificate, in addition to the information described in § 85.1, states: (i) The identification tag, tattoo, earnotch recognized by a breed association, or similar identification of each animal being moved; and (ii) that each animal to be moved: (A) Was subjected to an official pseudorabies serologic test within 30 days prior to the interstate movement and was found negative, the test date and the name of the laboratory conducting the test; or (B) is part of a currently recognized qualified pseudorabies negative herd and the date of the last qualifying test; or, (C) is part of a pseudorabies controlled vaccinated herd and is one of the offspring that was subjected to the official pseudorabies serologic test to achieve or maintain the status of the herd as a pseudorabies controlled vaccinated herd, and the date of the last test to maintain said status.

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[44 FR 10309, Feb. 16, 1979, as amended at 48 FR 57472, Dec. 30, 1983; 50 FR 47352, Nov. 15, 1985]

§ 85.8 Other interstate movements.

The Deputy Administrator may, upon request in specific cases, permit the interstate movement of livestock not otherwise provided for in this part under such conditions as he may prescribe to prevent the spread of pseudorabies. Veterinary Services intends that such authority be used only in situations and under circumstances presenting problems that could not have been reasonably anticipated in advance and in unique situations. Veterinary Services does not intend that such authority be used repeatedly to cover the same problem, but that the regulation be amended to conform with needed changes as they come to light.

§ 85.9 Interstate movement of swine semen and swine embryos for insemination of or implantation into swine.

Swine semen and swine embryos moved interstate for insemination of swine or implantation into swine shall be accompanied by a document issued by an accredited veterinarian stating that the donor swine are not known to be infected with or exposed to pseudorabies, were negative to an official pseudorabies serologic test within 30 days prior to the collection of the semen or embryos or were members of a qualified pseudorabies negative herd, and had not been exposed to pseudorabies within 30 days prior to the collection of the semen or embryos.

[44 FR 10309, Feb. 16, 1979, as amended at 50 FR 47353, Nov. 15, 1985]

§ 85.10 Permits and certificates

(a) Each permit, certificate or owner-shipper statement required under this part to accompany swine interstate shall be delivered with the swine to the consignee by the person delivering the swine.

(b) A copy of each permit or certificate issued in accordance with this part shall be sent by the person issuing such document to the State animal health official of the State of destination within 3 days of the issuance of the document.

(Approved by the Office of Management and Budget under control number 0579-0069)

[44 FR 10309, Feb. 16, 1979, as amended at 48 FR 57472, Dec. 30, 1983; 50 FR 47353, Nov. 15, 1985]

§ 85.11 Maintenance of records.

(a) The consignor of swine not vaccinated for pseudorabies and not known to be infected with or exposed to pseudorabies which are moved interstate directly to a feedlot, quarantined feedlot, quarantined herd, or to an approved livestock market for subsequent movement directly to a feedlot, quarantined feedlot or quarantined herd shall maintain records whereby individual swine can be traced to the farm of origin.[1]

(b) Such records shall be maintained for two (2) years after the swine are moved interstate by the consignor, and such records shall be made available to the State animal health official or Veterinary Services representative on request.

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[44 FR 10309, Feb. 16, 1979, as amended at 48 FR 57472, Dec. 30, 1983; 50 FR 47353, Nov. 15, 1985]

§ 85.12 Cleaning and disinfecting means of conveyance.

All means of conveyance used in connection with the interstate movement of pseudorabies infected or exposed livestock shall be cleaned and disinfected in accordance with § 76.30 of this chapter using one of the disinfectants registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 135 *et seq.*) with herpes virucidal claims. These disinfectants shall be used in accordance with directions on their labels accepted in connection with their registration.

§ 85.13 Cleaning and disinfecting livestock markets and other facilities.

Livestock markets and other facilities used in connection with the interstate movement of pseudorabies infected or exposed livestock shall be cleaned and disinfected in compliance with § 76.31 of this chapter using one of the disinfectants registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 135 *et seq.*) with herpes virucidal claims. These disinfectants shall be used in accordance with directions on their labels accepted in connection with their registration.

PART 89—STATEMENT OF POLICY UNDER THE TWENTY-EIGHT HOUR LAW

Sec.
89.1 Amount of feed.
89.2 Two or more feedings at same station.
89.3 Feeding, watering, and resting livestock in the car.
89.4 Watering.
89.5 Feeding pens.

AUTHORITY: 34 Stat. 607; 45 U.S.C. 71-74; 19 FR 74, as amended.

SOURCE: 28 FR 5967, June 13, 1963, unless otherwise noted.

§ 89.1 Amount of feed.

(a) Under normal conditions, the amount of feed designated in the following schedule will be considered as sustaining rations for livestock in transit when fed at the intervals required by the Twenty-Eight Hour Law:

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[1] Such records shall list: (1) The names and addresses of the consignor and consignee; (2) the identification tag, tattoo, earnotch recognized by a breed association, or similar identification of each animal moved; and (3) the date of the shipment.

Species and quantity of livestock	At first feeding station	At second and subsequent feeding stations
Cattle and beef type or range calves (for each car [1])	200 lbs. of hay [1, 2]	300 lbs. of hay.[1, 2]
Dairy calves (for each car deck [1])	100 lbs. of hay [1, 2]	150 lbs. of hay.[1, 2]
Horses and mules (for each car [1])	400 lbs. of hay [1, 2]	400 lbs. of hay.[1, 2]
Sheep and goats (for each car deck [1])	200 lbs. of hay [1, 2]	300 lbs. of hay.[1, 2]
Lambs and kids (for each car deck [1])	100 lbs. of hay [1, 2]	150 lbs. of hay.[1, 2]
Swine (for each carload lot, in single or double deck car, the amount of shelled corn [2] indicated):		
Lots of not more than 18,000 lbs	2 bushels	2 bushels.
More than 18,000 lbs. but not more than 21,000 lbs	2½ bushels	2½ bushels.
More than 21,000 lbs. but not more than 24,000 lbs	3 bushels	3 bushels.
More than 24,000 lbs. but not more than 27,000 lbs	3½ bushels	3½ bushels.
More than 27,000 lbs. but not more than 30,000 lbs	4 bushels	4 bushels.
More than 30,000 lbs.—proportionately larger amounts		

[1] The requirements set forth the sustaining rations for a full load of livestock in a railroad car 40 feet in length. The requirements for a full load of livestock in railroad cars of different sizes should be modified proportionately, i.e., a load of livestock transported in a car 50 feet in length would require an additional 25 percent of feed or 2.5 percent for each additional foot of car over 40 feet.

[2] Or the equivalent in other suitable feed. Dairy calves too young to eat hay or grain, or shipped without their dams, should be given a sufficient amount of prepared calf feed, milk, raw eggs, or other suitable feed. All feed should be of good quality.

(b) When the owner of a consignment of livestock desires that they be fed larger amounts of feed than those designated in paragraph (a) of this section for the particular kind and quantity of livestock, or the carrier believes that they should be fed larger amounts, the amounts to be fed should be agreed upon, if practicable, by the owner and the carrier at the time the animals are offered for shipment.

(c) When emergency conditions arise, such as severe changes in the weather, which increase the rigors of transportation, the livestock should receive amounts of feed, additional to those designated in paragraph (a) of this section, sufficient to sustain them until they arrive at the next feeding station or destination.

(d) When the movement of livestock is delayed en route so that the period of their confinement in the cars materially exceeds that specified by the Twenty-Eight Hour Law, the livestock should receive additional feed in proportion to such excess time.

§ 89.2 Two or more feedings at same station.

When livestock are held at a feeding station 12 hours after the last previous feed has been substantially consumed, they should again be fed the ration prescribed by § 89.1(a) for that station: *Provided, however,* That they may be held without such feeding for a period longer than 12 hours if the time they are so held, added to the time required to reach the next feeding station or destination, whichever is closer, would not ordinarily exceed 40 hours.

§ 89.3 Feeding, watering, and resting livestock in the car.

(a) Livestock should be unloaded into pens of the character described in § 89.5(a) for feeding, watering, and resting, unless there is ample room in the car for all of the animals to lie down at the same time.

(b) If livestock are watered in the car, adequate facilities should be provided and ample water furnished to insure all the animals an opportunity to drink their fill. In the case of hogs, water should be available for not less than 1 hour.

(c) Livestock unloaded for feed and water and returned to the car for rest should be allowed to remain in the pens not less than 2 hours.

(d) Livestock unloaded for water and returned to the car for feed and rest should be allowed to remain in the pens not less than 1 hour.

(e) When livestock are fed in the car, the feed should be evenly distributed throughout the car.

§ 89.4 Watering.

Livestock should be furnished an ample supply of potable water. Water treated with chemicals for industrial or boiler use, or taken from streams or ponds containing sewage, mud, or other objectionable matter should not be used. Troughs and other receptacles should be clean. In cold weather, the water should be free from ice.

§ 89.5 Feeding pens.

(a) Stock pens and other enclosures for feeding, watering, and resting livestock in transit should have (1) sufficient space for all of the livestock to lie down at the same time, (2) properly designed facilities for feeding and watering the livestock, (3) reasonably well-drained, clean, and safe floors of concrete, cinders, gravel, hard-packed earth, or other suitable material, and (4) suitable protection from weather reasonably to be expected in the region in which the pens are located.

(b) Care should be taken to protect livestock unloaded en route at a point having marked difference in temperature from that at the point from which they were shipped.

SUBCHAPTER D—EXPORTATION AND IMPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

PART 91—INSPECTION AND HANDLING OF LIVESTOCK FOR EXPORTATION

Subpart A—General Provisions

Sec.
91.1 Definitions.
91.2 Animals to be handled in compliance with regulations.
91.3 General export requirements.
91.4 Other movements and conditions.

Subpart B—Diagnostic Tests, Treatments

91.5 Cattle.
91.6 Goats.
91.7 [Reserved]
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Subpart C—Ports of Embarkation, Facilities; Health Certification

91.14 Ports of embarkation and export inspection facilities.
91.15 Inspection of animals for export.
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Subpart D—Inspection of Vessels and Accommodations

91.17 Accommodations for humane treatment of animals on ocean vessels.
91.18 Cleaning and disinfection of transport carriers for export.
91.19 Inspection of ocean vessels prior to loading.
91.20 General construction.
91.21 Ventilation.
91.22 Protection from heat of boilers and engines.
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91.24 Attendants.
91.25 Space requirements for animals on ocean vessels.
91.26 Concrete flooring.
91.27 Troughs and hayracks.
91.28 Stanchions and rails.
91.29 Hatches.
91.30 Defective fittings.

AUTHORITY: 21 U.S.C. 105, 112, 113, 114a, 120, 121, 134b, 134f, 612, 613, 614, 618, 46 U.S.C. 466a, 466b, 49 U.S.C. 1509(d); 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 42 FR 28990, June 7, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 91.1 Definitions.

Whenever in the regulations in this part the following terms are used, they shall be construed as follows:

(a) *Department.* The United States Department of Agriculture.

(b) *Veterinary Services.* The Veterinary Services, Animal and Plant Health Inspection Service of the Department.

(c) *Deputy Administrator.* The Deputy Administrator, Veterinary Services, or any other official of Veterinary Services to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(d) *Inspector.* An inspector of Veterinary Services.

(e) *Animals.* Horses, cattle (including American bison), sheep, swine, and goats.

(f) *Horses.* Horses, mules, and asses.

(g) *Roofing paper.* Any saturated roofing paper of a grade known to the trade as 30-pound roofing paper.

(h) *Official brucellosis vaccinate.* A female bovine animal vaccinated against brucellosis in accordance with the provisions prescribed in the Recommended brucellosis Eradication Uniform Methods and Rules, Chapter 1, part I-H, I, and J. The provisions of the Uniform Methods and Rules are hereby incorporated by reference.

(i) *Accredited veterinarian.* An accredited veterinarian as defined in Part 160 of this chapter.

(j) *Premises of origin.* The farm or other premises where the animals intended for export are being raised or assembled, or both, immediately before movement for export.

(k) *State of origin.* The State in which the premises of origin is located.

(l) *Origin health certificate.* An official document issued by a Veterinary Services representative or an accredited veterinarian at the point of origin of a shipment of animals to be moved under this part, which shows the identification tag, tattoo, or registration number or similar identification of each animal to be moved, the number, breed, sex, and approximate age of the animals covered by the document, the date and place of issuance, the points of origin and destination, the consignor, and the consignee, and which states that the animal or animals identified on the certificate meet the export health requirements.

§ 91.2 Animals to be handled in compliance with regulations.

No animals covered by the regulations in this part shall be exported to a foreign country except in compliance with the provisions in this part.

§ 91.3 General export requirements.

(a) All animals intended for exportation to a foreign country, except animals intended for exportation to Mexico or Canada, shall be accompanied from the State of origin of the export movement to the port of embarkation by an origin health certificate. All animals intended for exportation to Mexico or Canada shall be accompanied from the State of origin of the export movement to the border of the United States by an origin health certificate. The origin health certificates shall certify that the animals were inspected within the 30 days prior to the date of the movement of the animals for export, and were found to be sound, healthly, and free from evidence of communicable disease and exposure thereto. The origin health certificates shall be endorsed by an authorized Veterinary Services veterinarian in the State of origin. The origin health certificates shall individually identify the animals in the shipment as to species, breed, sex, and age, and if applicable shall also show registration name and number, tattoo markings, or other natural or acquired markings.

(b) *Inspection.* All animals in each export shipment, except animals intended for export to Mexico or Canada, shall have been inspected, tested, or treated in the manner prescribed in this part prior to the movement of the export shipment to the export inspection facility. All animals in each export shipment intended for export to Mexico or Canada shall have been inspected, tested, or treated in the manner prescribed in this part prior to the movement of the animals from the State of origin. The Deputy Administrator may, upon request of the appropriate animal health official of the country of destination, waive the tuberculosis and brucellosis tests referred to in §§ 91.5(a) and (b), 91.6(a)(1) and (2), and 91.9(a) of this part when he finds such tests are not necessary to prevent the exportation of diseased animals from the United States.

(c) *Testing.* All samples for tests required by §§ 91.5 through 91.13 for exportation of animals under this section shall be taken by an inspector or an accredited veterinarian in the State of origin of the export movement. Such samples shall be taken and tests made within the 30 days prior to the date of movement of the animals for export from the premises of origin, except that the Deputy Administrator may permit such sampling or tests to be made more than 30 days prior to the date of export, if required by the receiving country and the tuberculin test may be conducted within the 90 days prior to the date of the movement of the animals for export. The test for brucellosis shall be conducted in a cooperating State-Federal laboratory[1] in accordance with the Recommended Brucellosis Eradication Uniform Methods and Rules.

(d) *Movement in cleaned and disinfected carriers or containers.* The origin health certificate accompanying animals shall be accompanied by a statement from the issuing accredited veterinarian or inspector that the means of conveyance or container has been cleaned and disinfected since last used for animals with a disinfectant approved under § 71.10 of this chapter, prior to loading, or that the carrier or container has not previously been used in transporting animals.

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[1] A list of cooperating State-Federal laboratories may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, Hyattsville, Md. 20782.

(e) *Clean and disinfected facilities for unloading animals.* Animals intended for exportation to Mexico or Canada or enroute to a port of embarkation shall be unloaded only into a facility which shall have been cleaned and disinfected with a disinfectant approved under § 71.10 of this chapter, under the supervision of an inspector or an accredited veterinarian prior to such unloading. A statement certifying to such action shall be attached to the origin health certificate by the supervising inspector or accredited veterinarian.

(Approved by the Office of Management and Budget under control number 0579-0069)

[42 FR 28990, June 7, 1977, as amended at 44 FR 28298, May 15, 1979. Redesignated and amended at 45 FR 86412, Dec. 31, 1980; 48 FR 57472, Dec. 30, 1983]

§ 91.4 Other movements and conditions.

The Deputy Administrator, Veterinary Services, may, upon request in specific cases, permit the exportation of livestock not otherwise provided for in this part under such conditions as he may prescribe in each specific case to prevent the spread of livestock diseases and to insure the humane treatment of the animals while in transit.

[43 FR 27171, June 23, 1978. Redesignated at 45 FR 86412, Dec. 31, 1980]

Subpart B—Diagnostic Tests, Treatments

SOURCE: 45 FR 86412, Dec. 31, 1980, unless otherwise noted.

§ 91.5 Cattle.

In order to be eligible for export, cattle shall be tested with results as specified in this section, and the origin health certificate shall specify the type of tests conducted, the dates of the tests, and the results of the tests.

(a) *Tuberculosis.* All cattle over one month of age shall be negative to a caudal intradermal tuberculin test using 0.1 ml. of tuberculin with a reading obtained 72 hours (plus or minus six hours) after injection as prescribed in Veterinary Services Memorandum 552.15 "Instructions and Procedures for Conducting Tuberculin Tests in Cattle," section VIII A.[2]

(b) *Brucellosis.* All cattle over six months of age shall be negative to a test for brucellosis conducted as prescribed in "Standard Agglutination Test Procedures for the Diagnosis of Brucellosis" [3] or "Supplemental Test procedures for the Diagnosis of Brucellosis"; [3] except, that such tests are not required for official vaccinates of dairy breeds under 20 months of age, official vaccinates of beef breeds under 24 months of age, or steers and spayed heifers.

(c) *Treatment for ectoparasites.* All cattle, except those found free of ectoparasites or those intended for exportation for slaughter purposes to any foreign country shall be treated for ectoparasites within 30 days preceding the date of export. Such treatment shall be made using a pesticide registered by the Environmental Protection Agency for use in treating animals infested with the ectoparasite involved in accordance with the label requirements. Treatment shall be personally supervised and certified on the origin health certificate by an accredited veterinarian who shall be ready to apply an antidote if adverse side effects occur following treatment.

(Approved by the Office of Management and Budget under control number 0579-0069)

[45 FR 86412, Dec. 31, 1980, as amended at 48 FR 57472, Dec. 30, 1983]

§ 91.6 Goats.

(a) In order to be eligible for export, goats shall be tested with results as specified in this section, and the origin health certificate for such animals shall specify the type of test conducted, the date of the tests, and the results of the tests.

(1) *Tuberculosis.* All goats over 1 month of age shall be negative to a caudal intradermal tuberculin test using 0.1 ml. of tuberculin with a read-

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[2] Copies of this publication may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, Hyattsville, Maryland 20782.

[3] See footnote 4 to § 91.8.

ing obtained 72 hours (plus or minus 6 hours) after injection as prescribed in Veterinary Services Memorandum 552.15.

(2) *Brucellosis.* Dairy and breeding goats shall be negative to a plate or tube agglutination test for brucellosis as prescribed in "Standard Agglutination Test Procedures for the Diagnosis of Brucellosis." [2]

(3) No goat shall be exported if it is affected with or exposed to scrapie, or originated from, or has been on, any premises which then were infected or source flock premises,[4] or if it is the progeny, sire or dam, or a full or half brother or sister of any animal found to be affected with scrapie, or was moved from premises located in an area quarantined for scrapie.

(4) Goats exported for immediate slaughter need not comply with the requirements of paragraphs (a)(1), (2), (3), and (5) of this section.

(5) All goats intended for export shall be identified by eartags or tattoos approved by the Deputy Administrator,[5] except that goats for export to Canada or Mexico for immediate slaughter may be identified by flock brands.

(Approved by the Office of Management and Budget under control number 0579-0069)

[45 FR 86412, Dec. 31, 1980, as amended at 48 FR 57472, Dec. 30, 1983]

§ 91.7 [Reserved]

§ 91.8 Sheep.

(a) No sheep shall be exported if it is affected with or exposed to scrapie, or originated from, or has been on, any premises which then were infected or source flock premises,[4] or if it is the progeny, sire or dam, or a full or half brother or sister of any animal found to be affected with scrapie, or was moved from premises located in an area quarantined for scrapie.

(1) Sheep exported for immediate slaughter need not comply with the requirements of paragraph (a)(2) of this section.

(2) All sheep intended for export shall be identified by eartags or tattoos approved by the Deputy Administrator.[5] except that sheep for export to Canada or Mexico for immediate slaughter may be identified by flock brands.

§ 91.9 Swine.

(a) No swine shall be exported if they were fed garbage at any time. The swine shall be accompanied by a certification from the owner stating that they were not fed garbage, and that any additions to the herd made within the 30 days immediately preceding the export shipment, have been maintained isolated from the swine to be exported. All breeding swine shall be tested for and show negative test results to brucellosis by a test prescribed in "Standard Agglutination Test Procedures for the Diagnosis of Brucellosis" [2] or "Supplemental Test Procedures for the Diagnosis of Brucellosis".[2] The test results shall be classified negative in accordance with the provisions prescribed in the Recommended Brucellosis Eradication Uniform Methods and Rules, Chapter 2, Part II, G, 1, 2, and 3.

Subpart C—Ports of Embarkation, Facilities, Health Certification

§ 91.14 Ports of embarkation and export inspection facilities.

(a) The following ports which have export inspection facilities which satisfy the requirements of paragraph (c) of this section are hereby designated as ports of embarkation. All animals, except animals being exported to Mexico or Canada, shall be exported through said ports or through ports designated in special cases under paragraph (b) of this section:

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[2] See footnote 2 to § 91.5.

[4] Infected premises are those on which an animal has been found to be infected with scrapie. Source flock premises are those from which an affected animal was moved within 18 months or less prior to showing signs of scrapie.

[5] Information concerning eartags or tattoos approved by the Deputy Administrator may be obtained, upon request, from the Deputy Administrator, Animal and Plant Health Inspection Service, United States Department of Agriculture, Hyattsville, Maryland 20782.

(1) *California.*

(i) Los Angeles—airport and ocean port.

(A) Jet Pets, Inc., 9014 Pershing Drive, Plaza del Rey, CA 90291, (213) 823-8901.

(B) Steifel Bros. Livestock, 14380 South Euclid Avenue, Chino, CA 91710, (714) 597-1756.

(ii) San Francisco—airport and ocean port.

(A) Cow Palace, P.O. Box 34206, San Francisco, CA 94134, (415) 469-6000.

(B) Petair, 145 Bel Air Road, P.O. Box 2431, South San Francisco, CA 94080, (415) 877-0200.

(iii) Stockton—airport only.

(A) Hemet Flying Service, Stockton Municipal Airport, Stockton, CA 95204, (209) 982-1676.

(2) *Florida.*

(i) Miami—airport and ocean port.

(A) USDA Import-Export Center, 6300 N.W. 36th Street, P.O. Box 523054, Miami, FL 33152, (305) 526-2828.

(ii) Tampa—ocean port.

(A) Tampa Port Authority, 2703 E. 7th Avenue, Tampa, FL 33605, (813) 248-1924.

(3) *Hawaii.*

(i) Honolulu—airport and ocean port.

(A) Hawaii State Quarantine Station, 99-762 Moanalua Road, Aiea, Hawaii 96701, (808) 487-5351.

(4) *Illinois.*

(i) Chicago—airport only.

(A) C&R Midwest Quarantine Facilities, Ltd., Box 470, Route 31, Dundee, IL 60118, (312) 426-5009.

(5) *Indiana.*

(i) Indianapolis—airport only.

(A) Indiana Livestock Export Inspection Facility, Indianapolis International Airport, 7151 Powers Drive, Indianapolis, IN 46241, (317) 248-9211.

(6) *Kentucky.*

(i) Greater Cincinnati Airport.

(A) Newton Paddocks (horses only), Barn No. 8, Newton Pike, Lexington, KY 40511, (606) 253-3456.

(7) *Louisiana.*

(i) New Iberia—airport only.

(A) Acadiana Regional Airport, Star R-3, Box 390-H (ARA), New Iberia, LA 70560, (318) 365-7204.

(8) *Minnesota.*

(i) Minneapolis/St. Paul—airport only.

(A) American Livestock Export Company, 25789 Northfield Blvd., Hampton, MN 55031, (612) 831-3873.

(9) *New York.*

(i) Newburgh—airport only.

(A) Stewart Airport, Newburgh, NY 12550, (914) 564-7200.

(ii) New York—airport and ocean port.

(A) ASPCA, Bldg. 189, J. F. Kennedy International Airport (Cargo Area), Jamaica, NY 11430, (212) 656-6042.

(B) Alex Nichols Agency (horses only), P.O. Box 283, Glen Head, NY 11545, (516) 626-9100.

(10) *Pennsylvania.*

(i) Harrisburg—airport only.

(A) Penn. Holstein Farm Export Inspection Facility, R.D. #1, Middletown, PA 17057, (717) 944-1374.

(11) *Oregon.*

(i) Portland—airport and ocean port.

(A) Northwest Quarantine Station, P.O. Box 17095, Portland, OR 97217, (503) 289-8876.

(12) *Puerto Rico.*

(i) San Juan—airport.

(A) El Commandante Race Track (Horses Only), P.O. Box 1304, Rio Piedras, PR 00929, (809) 724-6060.

(13) *Texas.*

(i) Brownsville—airport, ocean port, and border port.

(A) Texas Department of Agriculture, Livestock Inspection Facility, International Airport, Brownsville, TX 78520, (512) 546-5135.

(ii) Del Rio—border port.

(A) Texas Department of Agriculture, Livestock Export Facility, Box 1046, Del Rio, TX 78840, (512) 775-1518.

(iii) Eagle Pass—border port.

(A) Texas Department of Agriculture, Livestock Export Facility, Box 1164, Eagle Pass, TX 78852, (512) 773-2359.

(iv) El Paso—border port.

(A) Texas Department of Agriculture, Livestock Export Facility, 10800 Socorro Drive, El Paso, TX 79927, (915) 543-7419.

(v) Houston—airport and ocean port.

(A) Texas Department of Agriculture, Livestock Export Facility, Box

60107, AMF, Houston, TX 77205, (713) 443-2447.

(vi) Laredo—border port.

(A) Texas Department of Agriculture, Livestock Export Facility, Route 1, Box 67-P, Laredo, TX 78040, (512) 722-6308.

(14) *Virginia.*

(i) Richmond—airport and ocean port.

(A) American Marketing Services, Inc., 1301 Hermitage Road, Richmond, VA 23220, (804) 359-4433.

(15) *Washington.*

(i) Moses Lake—airport only.

(A) Port of Moses Lake, Grant County Airport, Terminal Bldg., Moses Lake, WA 98837, (509) 762-5363.

(ii) Seattle—airport and ocean port.

(A) S&W Export Ltd., P.O. Box 68892, Seattle, WA 98188, (206) 248-2360.

(b) In special cases, other ports may be designated as ports of embarkation by the Deputy Administrator, with the concurrence of the Director of Customs, when the exporter can show to the satisfaction of the Deputy Administrator that the animals to be exported would suffer undue hardship if they are required to be moved to a port of embarkation listed in § 91.14(a). Such ports shall be designated only if the inspection facilities are approved as meeting the requirements of paragraph (c) of this section.

(c) *Standards for export inspection facilities.* Inspection facilities located at ports of embarkation designated under paragraph (a) of this section, and inspection facilities designated in special cases under paragraph (b) of this section, shall meet the following requirements:

(1) *Materials.* Floors of pens, alleys, and chutes shall be made of impervious materials and finished so as to be skid-resistant. Impervious floors are those constructed of a material that resists the absorption of fluids. Such materials include concrete, asphalt, brick, metal, or other synthetic material that may be cleaned and disinfected. Fences, gates, and other parts of the facility shall be constructed of wood, metal, or other material that will securely restrain the animals in a safe and humane manner. The facility shall have a roof adequate to protect the animals from inclement weather over at least three-fourths of the pens and alleys and over all of the inspection area.

(2) *Size.* The facility shall be large enough to accommodate all the animals in a single export shipment at one time. A minimum space twice the rate required per animal in § 91.25(b) shall be provided for each animal.

(3) *Inspection implements.* The facility shall have a separate area available for inspection and identification of the animals. Pens and animal restraining devices shall be provided in this area which are sufficient for the inspection and identification of each animal. Pens or yards shall be provided for appropriate segregation, treatment, or both, of animals of questionable health status apart from animals qualified for exportation under this part.

(4) *Cleaning and disinfection.* The facility and equipment shall be cleaned and disinfected with a disinfectant permitted under § 71.10 of this chapter under the supervision of a Federal inspector prior to entry of each export shipment into the export inspection facility. Personnel tending the animals shall, if they come in contact with animals outside of the facility, be required to change or sanitize their outer clothing and footwear.

(5) *Feed and water.* An ample supply of potable water shall be made available to the animals intended for export, and in cold weather such water shall be kept free of ice. Feed and feeding facilities appropriate for the animals intended for export shall be provided.

(6) *Access; approval of arrangements.* Access to all parts of the facility shall be allowed to a Veterinary Services inspector at all times, day or night, and the arrangement for handling the animals shall be subject to the approval of the inspector. Approval shall be granted by the inspector if he finds that such arrangements will not permit the dissemination of communicable diseases of livestock to the animals in the export shipment.

(7) *Testing and treatment.* Testing and treatment of animals in export inspection facilities shall be performed by an accredited Veterinarian under

the supervision of a Veterinary Services veterinarian. Tests related to Veterinary Services animal disease programs shall be performed in accordance with the Recommended Brucellosis Eradication Uniform Methods and Rules.

(8) *Location.* The arrangement and location of the facilities shall provide for the isolation of all animals in the facility from contact with any other animals. Isolation of separate export shipments in the facility shall be at the discretion of the Veterinary Services inspector.

(9) *Disposal of animal wastes.* The application for approval of an export inspection facility shall be accompanied by a certification from the authorities having jurisdiction over environmental affairs in the locality of the facility stating that the facility complies with the applicable State and local regulations or ordinances and the requirements, if any, of the United States Environmental Protection Agency, regarding disposal of animal wastes.

(10) *Lighting.* The facility shall be equipped with artifical lighting to provide not less than 70 foot candle power in the inspection area and not less than 40 foot candle power in the remainder of the facility.

(11) *Office and rest room.* A suitable office and adequate rest room facilities shall be provided at the export inspection facility site for use of the inspectors.

(d) *Approval and denial, revocation, or suspension of approval.* Approval of each export inspection facility for designation under paragraph (a) of this section and in special cases under paragraph (b) of this section, shall be obtained from the Deputy Administrator. Approval of an export inspection facility under paragraph (a) or (b) will be denied or revoked for failure to meet the standards in paragraph (c) of this section. A written notice at least 60 days prior to the date of any proposed revocation and a written notice of any proposed denial shall be given to the operator of the facility and he will be given an opportunity to present his views thereon. Such notice shall list in detail the deficiencies concerned. Pending a final determination, approval of any facility may be denied or suspended by the Deputy Administrator when he has reason to believe that the facility does not meet such standards. Approval of a port of embarkation in connection with the designation of an export inspection facility in a special case shall be limited to the special case for which the designation was made.

[42 FR 28980, June 7, 1977, as amended at 44 FR 28298, May 15, 1979; 44 FR 42670, July 20, 1979; 45 FR 67308, Oct. 10, 1980. Redesignated and amended at 45 FR 86413, Dec. 31, 1980; 46 FR 35913, July 13, 1981; 47 FR 56984, Dec. 22, 1982; 48 FR 44061, Sept. 27, 1983; 48 FR 52691, Nov. 22, 1983; 49 FR 9409, Mar. 13, 1984; 49 FR 24014, June 11, 1984; 49 FR 36078, Sept. 14, 1984; 50 FR 27930, July 9, 1985; 50 FR 29205, July 18, 1985; 50 FR 40328, Oct. 3, 1985]

§ 91.15 Inspection of animals for export.

(a) All animals offered for exportation to any foreign country, except Mexico or Canada, shall be inspected by a Veterinary Services veterinarian at an export inspection facility at a port designated in § 91.14(a), or at a port or inspection facility designated by the Deputy Administrator in a special case under § 91.14(b).

(b) Such animals shall be held for a period of not less than 5 hours at the port of embarkation or export inspection facility during which time the animals shall be given a careful visual health inspection. Sorting, grouping, identification, or other handling of the animals by the exporter may be before or after this period of time. If individual clinical inspection of an animal is deemed necessary by a Veterinary Services veterinarian for the purpose of determining its health status, such inspection may be made during this period of time or thereafter.

(c) *Feed and water.* All animals shall be allowed a period of at least 5 hours for rest at the export inspection facility, with adequate feed and water available, before movement to an ocean vessel or aircraft for loading for export. (This may be the same period required by paragraph (b) for health inspection.) However, feed and water will not be required if the animals were transported to the export inspection facility in a carrier in which adequate feed and water were provided and if sufficient evidence is presented to a Veterinary Services veterinarian that the animals, if under 30 days of age, will arrive in the country of destination within 24 hours after they were last fed and watered, in the United States, or in the case of other animals within 36 hours after they were last fed and watered in the United States

[42 FR 28990, June 7, 1977, as amended at 44 FR 28299, May 15, 1979. Redesignated at 45 FR 86413, Dec. 31, 1980]

§ 91.16 Certification of animals for export.

If, upon inspection by a Veterinary Services veterinarian at the export inspection facility, the animals offered for export are found to be sound, healthy, and free from evidence of communicable disease or exposure thereto, an export certificate, VS Form 17-37, shall be issued by said Veterinary Services veterinarian and shall contain a statement to that effect.

[42 FR 28990, June 7, 1977. Redesignated at 45 FR 86413, Dec. 31, 1980]

Subpart D—Inspection of Vessels and Accommodations

§ 91.17 Accommodations for humane treatment of animals on ocean vessels.

(a) The owner or operator of an ocean vessel carrying animals from the United States to a foreign country shall provide, for such animals, feed and water, space, ventilation, fittings, and other facilities aboard the carrier as set forth in this part. For animals embarked for a voyage which will be of more than 36 hours duration, there shall be provided to the satisfaction of the inspector sufficient amounts of suitable feed and fresh water, and proper accommodations shall be provided on board for storage and distribution of the water and feed. The feed shall not be exposed to the weather at sea. However, such feed and water shall not be required if it is determined by the Veterinary Services veterinarian that the animals, if under 30 days of age will arrive in the country of destination within 24 hours after they were last fed and watered in the United States, or, in the case of other animals, within 36 hours after they were last fed and watered in the United States.

(b) Owners masters, or operators of such vessels shall not accept for transportation any animal that in the judgment of the Veterinary Services veterinarian is in an unfit condition to withstand the rigors of such transportation. Further, no animal intended for export shall be placed aboard any ocean vessel, unless in the opinion of the inspector the loading arrangements, fittings, ventilation systems, and the arrangements provided by the vessel for their use reasonably assure arrival of a viable animal in the country of destination. Halters, ropes, or other suitable equipment provided for the handling and tying of horses shall be found to be satisfactory by the Veterinary Services veterinarian to assure humane treatment of the animals.

[42 FR 28990, June 7, 1977. Redesignated at 45 FR 86413, Dec. 31, 1980]

§ 91.18 Cleaning and disinfection of transport carriers for export.

All fittings, utensils and equipment, unless new, to be used in the loading, stowing, or other handling of animals aboard surface vessels under the provisions of this part, shall first be cleaned and disinfected under the supervision of an inspector before being used for, or in connection with, the transportation of animals from any United States port. Such disinfection of halters, ropes, and similar equipment used in handling and tying of animals shall be by immersion in an approved disinfectant. When the surface vessel has last been used to carry livestock to or from a foot-and-mouth disease infected country, the approved disinfectant shall be a freshly prepared solution of:

(a) Sodium carbonate (4 percent) in the proportion of 1 pound to 3 gallons of water.

(b) Sodium carbonate (4 percent) plus sodium silicate (0.1 percent) in the proportion of 1 pound of sodium carbonate plus sodium silicate to 3 gallons of water, or

(c) Sodium hydroxide (Lye) prepared in a fresh solution in the proportion of not less than 1 pound avoirdupois of sodium hydroxide of not less than 95 percent purity to 6 gallons of water, or one 13½-ounce can to 5 gallons of water.[7]

For carriers returning from other foreign countries, the approved disinfectant shall be a disinfectant permitted for use under § 71.10, Part 71 of this chapter.

[42 FR 28990, June 7, 1977. Redesignated and amended at 45 FR 86413, Dec. 31, 1980]

§ 91.19 Inspection of ocean vessels prior to loading.

It shall be the responsibility of the owners or the masters of an ocean vessel intended for use in exporting livestock to present the vessel to an inspector of Veterinary Services at a United States port of embarkation or at the descretion of the Deputy Administrator, upon request of the exporter, transporting company, or their agent, at a foreign port, for an inspection to determine if the fittings aboard the vessel are in compliance with the provisions of this part. A notarized statement from an engineering concern shall be required to certify to the rate of air exchange in each compartment. Such notarized statement shall be required upon first use of such vessel: *Provided*, That such notarized statement may again be required by the Deputy Administrator if substantive changes in fittings aboard the vessel have been made since the vessel was last certified.

[42 FR 28990, June 7, 1977. Redesignated at 45 FR 86413, Dec. 31, 1980]

§ 91.20 General construction.

A variety of construction materials such as wood, metal plate, or pipe may be used for stalls, crates, or pens aboard ocean vessels. Pipe fittings have the advantage of smooth surfaces, easy maintenance, long range economy and spaces between pipe rails to allow for feeding, watering, cleaning and better ventilation. Material used for stalls, crates, or pens shall be properly formed, closely fitted, and rigidly secured in place. Special care shall be taken to design and finish all edges, welds, and hardware that are accessible to animals. A combination of wood and steel pipe or other steel profile construction may be accepted if the construction complies with the regulations in this part. Where the sides of pens are adjacent to the ship's sides which have steel casing, frames, stays or similar fittings, the carrier shall cover these profiles with wooden battens of at least 2 inch thick lumber or plywood of similar strength to prevent animals from injury.

[42 FR 28990, June 7, 1977. Redesignated at 45 FR 86413, Dec. 31, 1980]

§ 91.21 Ventilation.

Each underdeck compartment on which animals are being transported aboard an ocean vessel shall be equipped with a system of mechanical ventilation that will furnish a complete change of air in each compartment every 2 minutes when deck height[8] is less than 8 feet and every 2½ minutes when the deck height[8] exceeds 8 feet. Spare motors and fans shall be available on board, for replacement or repair of the ventilation system during the voyage. A spare motor and fan of an approved type in working order shall be aboard the vessel for each type of motor or fan used. Net pen space in any compartment shall not exceed 80 percent of the deck area.

[42 FR 28990, June 7, 1977. Redesignated at 45 FR 86413, Dec 31, 1980]

§ 91.22 Protection from heat of boilers and engines.

No animals shall be stowed along the alleyways leading to the engine or boiler rooms unless the sides of said engine or boiler rooms are covered by a tongue and groove tight sheathing producing a 3-inch-wide air space except that on ships powered with internal combustion engines this sheathing may not be required at the discretion of the inspector.

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[7] Due to the extreme caustic nature of sodium hydroxide solution, precautionary measures such as the wearing of rubber gloves, boots, raincoat, and goggles should be observed. An acid solution such as vinegar shall be kept readily available in case any of the sodium hydroxide solution should come in contact with the body.

[8] Deck height is the height from the ceiling to the floor.

[42 FR 28990, June 7, 1977. Redesignated at 45 FR 86413, Dec. 31, 1980]

§ 91.23 Loading ramps and doors.

(a) Ramps connecting one deck of a ship to another shall have a clear width of 3 feet and a clear height of not less than 6 feet 6 inches. The incline of the ramps shall not exceed 1:2 (26½°) between the ramps and the horizontal plane. The ramps shall be fitted with footlocks of approximately 2" x 2" lumber and spaced no more than one foot apart. The ramps shall have side fencing not less than 5 feet in height. Side doors in ship's shell plating through which livestock are to be loaded shall have a height of not less than 6 feet for cattle and 6 feet 6 inches for horses.

(b) Alleyways running fore and aft on the ocean vessel that are used for feeding, watering, and loading animals, including horses in box stalls, shall have a minimum width of 3 feet. However, for a distance not to exceed 8 feet at the end of alleyways in the bow and the stern of ship, and where obstructions of less than 3 feet in length occur, the width may be reduced to a minimum of 24 inches. A sufficient number of athwartship alleyways at least 24 inches in width shall be provided to afford ready access to scuppers and to ends of alleyways running fore and aft. However, on exposed decks where scuppers and the end of fore and aft alleyways are readily accessiable athwartship alleyways are not required and if the alleyways are to be used for feeding or watering livestock, but not for loading or unloading of livestock, such alleyways shall have a minimum width of 28 inches.

[42 FR 28990, June 7, 1977. Redesignated at 45 FR 86413, Dec. 31, 1980]

§ 91.24 Attendants.

It shall be the responsibility of the captain of the ocean vessel to carry at least three men on board the vessel who are experienced in the handling of the kind/kinds of livestock to be carried, and a sufficient number of attendants, satisfactory to the inspector or the Veterinary Services' veterinarian at the port embarkation to insure proper care of the animals: *Provided, however,* That only one person experienced in the handling of the kind/kinds of livestock to be carried and a sufficient number of attendants, satisfactory to the Veterinary Services' veterinarian at the port of embarkation, to insure proper care of the animals must be carried on board the ocean vessel if less than 800 head of livestock are carried.

[42 FR 28990, June 7, 1977, as amended at 43 FR 27171, June 23, 1978. Redesignated at 45 FR 86413, Dec. 31, 1980]

§ 91.25 Space requirements for animals on ocean vessels.

(a) *General requirements.* A general space requirement for any individual animal in stalls or crates on ocean vessels shall be six inches more in height, depth, and width than the measurements of the animal concerned. The number of animals in each stall, pen or other container, the cubic inches of air available for each animal, and the ventilation capability of the transporting carrier are other criteria used to determine final space requirements for each animal. Guidelines of space requirements for storage of animals in pens are listed in paragraphs (b) and (c) of this section. Final determination of space needed and manner of loading of animals for export shipment will be made by the inspector or the Veterinary Services veterinarian at the port of embarkation, based upon the size and type of animals presented, weather, destination, route, and means of transportation employed for the export shipment.

(b) *Space guidelines:*

	Space in square feet allowed per animal—
Animal weight, pounds:	
100	4.0
150	5.0
200	6.0
250	6.9
300	7.9
350	8.9
400	9.9

	Space in square feet allowed per animal—
450	10.9
500	11.8
550	12.5
600	13.2
650	13.9
700	14.6
750	15.3
800	15.9—
850	16.6
900	17.3
950	17.8
1,000	18.4
1,050	18.9
1,100	19.4
1,150	19.9
1,200	20.4
1,250	21.0
1,300	21.5
1,350	22.0
1,400	22.7
1,450	23.3
1,500	24.0
1,550	24.6
1,600	25.3
1,650	25.9
1.700	26.6
1,750	27.2
1,800	27.8

(c) ***Space guidelines for containers.*** **Containers used aboard containerized ocean vessels measure 8 feet in width outside but vary from 7 feet 3 inches to 7 feet 9 inches in width inside and from 17 feet to 40 feet in length. For such containers the space requirements and minimum pen widths shown in the following charts shall be used whenever the length of the animal exceeds the width of the container. For ready measurement of dairy cattle only, the distance from the withers to the pin bone multiplied by 1.65 gives the approximate total length. Length of other cattle and large animals will require measurement of their total length. Other animals larger than those shown in the following charts shall be stowed subject to the approval of the inspector or the Veterinary Services veterinarian at the port of embarkation. Maximum inside length of container pens shall be 12 feet 9 inches.**

Weight	Square feet per head	3 head		4 head	
		Square feet	Width	Square feet	Width
CONTAINERS 7'9" IN WIDTH					
800	18.5			74.0	9'7"
850	19.5			78.0	10'1"
900	20.4	61.2	7'11"	81.6	10'6"
950	21.4	64.2	8'4"	85.6	11'1"
1,000	22.4	67.5	8'9"	90.6	11'7"
1,050	23.4	70.2	9'1"	93.6	12'1"
1,100	24.5	73.5	9'6"	98.0	12'8"
1,150	25.5	76.2	9'10"		
1,200	26.5	79.5	10'3"		
1,250	27.4	82.2	10'6"		
1,300	28.4	85.2	11'0"		
1,350	29.6	88.8	11'6"		
1,400	30.8	92.4	12'0"		
1,450	31.9	95.7	12'4"		
1,500	32.9	98.7	12'9"		
CONTAINERS 7'3" IN WIDTH					
700	16.3			65.2	9'0"
750	17.5	52.2	7'3"	70.0	9'8"
800	18.9	56.7	7'9"	75.6	10'5"
850	20.1	60.3	8'3"	80.4	11'1"
900	21.3	63.9	8'9"	85.2	11'9"
950	22.3	66.9	9'2"	89.2	12'4"
1,000	23.7	71.1	9'8"		
1,050	24.8	74.1	10'1"		
1,100	26.0	78.6	10'9"		
1,150	27.1	81.3	11'3"		
1,200	28.4	85.5	11'10"		

Weight	Square feet per head	3 head		4 head	
		Square feet	Width	Square feet	Width
1,250	29.6	88.8	12′3″	....	....
1,300	30.9	92.7	12′9″	....	....

(d) *Special requirements.* If an animal to be loaded on an ocean vessel is in the third trimester of pregnancy or the route of the carrier will be into or through a tropical area,[9] the space required for each animal shall be increased by 10 percent. If the animal to be exported is in the third trimester of pregnancy and the route of the vessel will be into or through such area, the space required for such animal shall be increased by 20 percent. (See also paragraph (g). In addition, hospital pens measuring not less than 3 feet by 8 feet for each animal shall be provided at the rate of 3 such pens for each 100 head loaded, except as provided for horses in paragraph (e) of this section.

(e) *Size of stalls or pens for horses on ocean vessels.* Space for horses in pens on ocean vessels shall not be less than 6 feet 6 inches from roof or beams overhead to floor underfoot. Space containing up to 120 square feet may be used for stowage of horses and shall be at least 8 feet but not more than 9 feet in width (thwartship) except that upon approval of the inspector or the Veterinary Services veterinarian at the port of embarkation, pens 7 feet wide may be allowed for medium-sized horses. Single stalls shall be not less than 2½ feet wide. Mares in foal shall be shipped only in separate stalls which shall be not less than 8 feet long by 3 feet wide and for mares due to foal en route and for stallions, stalls shall not be less than 8 feet long by 5 feet wide and shall be readily accessible to ship personnel. Extra stalls suitably located shall be provided in each compartment or on decks where horses are carried so that adequate hospital space can be made available for any horses that become sick or disabled aboard ship. The number of such stalls shall be as follows: One for the first 4 to 10 horses shipped, another for any number in excess of 10 up to and including 25, and still another for each additional 25 horses or fraction thereof.

(f) (1) Except as provided in paragraph (c) of this section, space in pens on ocean vessels for cattle weighing 1000 pounds or more shall be no less than 8 feet nor more than 9 feet in width and 6 feet 3 inches from roof or beams overhead to flooring underfoot, except that when floors are raised over pipes and similar obstructions, a height of not less than 6 feet may be permitted at the discretion of the inspector. Pens for cattle shall not exceed 120 square feet. When any such pen includes stanchions, sounding tubes, ventilators, and other obstructions, 20 percent more space for each animal shall be required.

(2) Single stalls in ocean vessels for cattle weighing 1000 pounds or more shall be not less than 8 feet in length by 3 feet in width.

(3) Calves and yearlings may be stowed in pens or stalls at the discretion of the inspector or the Veterinary Services veterinarian at the port of embarkation.

(g) *Space for sheep, goats, and swine on ocean vessels.* Space for sheep, goats, and swine on ocean vessels shall not be less than 3 feet in height and the length and width of pens shall not exceed 15 x 8 feet. An increase of 50 percent square footage shall be required for animals in the third timester of pregnancy, notwithstanding other provisions in paragraph (d).

[42 FR 28990, June 7, 1977. Redesignated and amended at 45 FR 86413, Dec. 31, 1980]

§ 91.26 Concrete Flooring.

(a) Pens aboard an ocean vessel shall have a 3 inch concrete pavement, proportioned and mixed to give 2000 psi. compressive strength in 28 days. The pavement shall have a broom or rough finish. Steel angle bars may be used for footlocks if they are mounted into the flooring in such a way that, at the same time, the bars serve as gutterways. The angle bars shall not be less than 2 inches by 2 inches and 5/16 inches in thickness, and spaced on 12 inch centers running for and aft on the vessel.

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[9] The area situated between the Tropic of Cancer and the Tropic of Capricorn.

(b)(1) *Horses and cattle.* Flooring shall be laid athwartship and secured by placing ends beneath the under side of foot and rump boards or under a 2" x 4" strip nailed along these boards. Floors may be either of two types, flush or raised. The flush type shall be constructed of not less than 1" thick limber laid flat on the deck. The raised type shall be constructed of not less than 2" thick lumber nailed to scantlings of at least 2" x 3" dimensions laid 2 feet 6 inches apart. If desired, flooring may be laid in portable sections. Flooring will not be required on ships with wooden decks provided footlocks are secured to the decks. Cement or composite material diagonally scored one-half inch deep may be used on iron decks instead of wooden flooring if the footlocks are molded in the same and bolted to the deck.

(2) *Sheep, goats, and swine.* Flooring for sheep, goats, and swine shall be the same as prescribed in this section for horses and cattle, except that the raised flooring need not be greater than 12 inch in thickness.

(3) *Drainage.* Provisions shall be made for drainage of urine and surface water from all parts of the vessel used for carriage of animals including sufficient scuppers. A walkway shall provide easy access to the scuppers.

(c)(1) *Horses and cattle.* In pens for horses or cattle, there shall be four footlocks of 1" x 4" lumber laid fore and aft with flat side down, and so placed as to provide in-between spaces of 12, 14, 26, and 14 inches, beginning at inside of the footboard. Additional footlocks shall be added at 14 inch intervals in pens having a depth of 9 feet or more. They shall be well secured with nails of a length that will permit 1 inch clinch in 1 inch flooring and 2 inch penetration in 2 inch flooring.

(2) *Sheep, goats, and swine.* Footlocks in pens for sheep, goats, and swine shall be of not less than 1" x 2" lumber, four to each pen, equally distributed and laid in the manner prescribed in paragraph (c)(1) of this section for horses and cattle.

[42 FR 28990, June 7, 1977. Redesignated at 45 FR 86413, Dec. 31, 1980]

§ 91.27 Troughs and hayracks.

All stalls and pens aboard an ocean vessel shall be equipped with proper troughs for feeding and watering animals as provided in this section. Racks or nets furnished for feeding hay shall be of a type acceptable to the inspector. The feeding of hay to the animals on ocean vessels may be by means of dispensing the hay from racks or nets or by placing the hay on the floor of the pens in which the animals are confined.

(a) *Horses and cattle.* Troughs may be constructed of metal or wood and may be either removable or fixed. The space between the first footlock and footboard may be utilized for feeding cattle, provided a 2" x 4" piece of lumber is affixed along the top surface of said footlock so that it, together with the footboard and the battens, will form an enclosure. If wooden troughs are used for feeding, an adequate supply of buckets or other metal containers shall be provided for the proper watering of the animals.

(b) *Sheep, goats, and swine.* Pens for these animals shall have feed troughs not less than 8 inches wide and shall be equipped with proper receptacles for watering. Pens for sheep and goats shall also have ample hayracks suitable for these animals.

[42 FR 28990, June 7, 1977. Redesignated at 45 FR 86413, Dec. 31, 1980]

§ 91.28 Stanchions and rails.

(a)(1) Pipes used for stanchions and rails for pens aboard an ocean vessel shall be made of zinc coated, galvanized, extra strong, medium carbon steel. Steel pipes or other steel profiles shall consist of not less than 4 pipes or profiles, the upper one to have 3 inch diameter and the others a diameter of not less than 2½ inches. Stanchions shall not be of less than 3½ inches diameter; shall not be of less than 5/16 inch thickness and shall not be placed more than 8 feet apart center to center.

(2) Threaded pipe connections shall not be used. All parts shall be cut from factory fabricated, seamless pipe.

(3) Bolt and pin holes shall not be drilled to more than 1/32 inch oversize. Holes shall be properly located and centered on pipe.

(4) Pipe shall not be deformed or weakened by welding such items as reinforcing rods or hinges thereto. Welding shall be used for such attachment to be exposed in the finished work. Pins, plates, and parts other than pipe shall be made of galvanized steel. All areas where galvanizing of the steel has eroded or has been damaged shall be finished with a rust preventative.

(5) Pipe rails shall be placed in proper alignment with tops of all gates at the same height.

(b) All gates of animal pens aboard an ocean vessel shall have smooth finished surfaces and the pivot-pins shall have a minimum diameter of ¾ inch.

(c) Animals may be carried on upper decks of an ocean vessel in space abutting the outside rails or bulwarks only if such rails or bulwarks are 3 feet or more in height from the deck and are of sufficient strength to hold the necessary fittings securely or if the space available is sufficient to permit securing the required fittings to provide the necessary strength. When animals are carried on upper decks, bulkheads shall be erected at all unprotected ends of stalls.

(d)(1) *Cattle and horses.* Rail stanchions for pens aboard an ocean vessel for cattle or horses shall be constructed of not less that 4" or 6" lumber set 5 feet apart on centers secured to the ship's rail or bulwark with ⅝ inch or larger bolts or collars and with heels raced to the sheer streak or waterway. Inboard stanchions of 4" x 6" lumber shall be set in line with the rail stanchions and properly braced: *Provided, however,* That the method of securing and bracing of stanchions may be modified as approved by the underwriter of the cargo bureau, and the inspector. Information concerning the modifications shall be made available to Veterinary Services, at its request. On open rail ships, spaces between the rails shall be blocked out to permit the affixing of outside planking. If supplementary stanchions are required for rump boards, these shall not be less than 3" x 4" in size and shall be secured to beams and decks as outlined above. On upper deck fittings at ends of unprotected stalls, a stanchion not less than 3" x 4" in size shall be similarly spaced and secured to beams and decks and properly braced. Stanchions on underdecks shall be constructed, spaced, and secured in the same manner as upper deck fittings.

(2) *Sheep, goats, and swine.* Stanchions for single or double tier pens for sheep, goats, and swine shall be constructed of not less 3" x 4" lumber set at not greater distance than 5 feet on centers and secured as outlined in paragraph (d)(1).

(e) For all animals, two beams of 2" x 6" lumber shall be bolted on each side of the stanchions using ⅝ inch bolts, nuts, and washers. Beams shall extend from outside planking to at least 2 feet beyond the line of the breast boards unless the beams butt on the ship's deck fittings. Two beams of 2" x 6" lumber shall be used to support the roof of single tier pens on exposed decks and the floor of double tier pens on all decks.

(f) All pens for carrying animals on exposed decks aboard an ocean vessel shall be roofed with not less than 1 inch thick, watertight lumber extending from outside planking to at least 2 feet beyond the line of breast boards: *Provided,* That, if tongue and grooved lumber is used, it must be caulked or covered so that it is watertight or if square edged lumber is used it shall be covered with a saturated roofing paper known to the trade as 30 pound roofing paper and shall be securely battened.

(g) All pens for carrying animals on exposed decks shall be provided with outside planking of not less than 1⅛ inch tongue and groove lumber, laid fore and aft of ship, driven tightly together and securely nailed to backs of stanchions in a manner to cover all open spaces properly. However, during warm weather the top course planking may be left off in order to allow a free circulation of air. On vessels with closed bulwarks, the outside planking shall extend not less than 6 inches below the upper edge of the bulwark.

(h)(1) *Horses.* All stalls and pens for horses shall be equipped with breast boards of no less than 2" x 10" dressed lumber with the top edge placed 3 feet 10 inches from the floor and securely nailed to the stanchions. Where butting occurs, the joints are to be on the stanchions and shall be covered with metal plates 3 inches square or 5 inches in diameter and not less than ¼ inch in thickness. A ⅝ inch bolt shall then be passed through the plate, joint, and stanchion and securely fastened with a nut. All breast boards shall have 1 inch holes bored through them at proper distances for tying animals. An occassional pen shall be provided with a removable breast board in order that animals may be loaded into and removed from the stalls and pens. All stalls and pens shall be provided with foot boards of not less than 2" x 10" lumber securely nailed or bolted to the stanchions. At the discretion of the inspector, small ponies, asses, small mules, mares with foal at foot, young unbroken horses or gentle horses of any size may be stowed loose in pens. In these cases, a sufficient number of finished 2" x 10" lumber shall be placed between the breast and foot boards to effectively contain the animals.

(2) *Cattle.* All stalls and pens for cattle shall be provided with boards as required for horses in paragraph (a), except that the front or breast boards shall be constructed in sets of three or more boards of 2" x 10" dressed lumber separated by 3 inch spacers and placed on the foot board so that the front of the pen extends 48 inches or more in height from the floor. One or more of the breast boards may be left off if feed or water troughs are to be mounted externally.

(3) *Sheep, goats, and swine.* Front boards in pens for sheep, goats, and swine shall be of not less than 1" x 6" pieces of lumber approximately spaced and extending to the proper height for these species of animals. Provision shall be made for removing a section of front boards to allow entry of animals into pens or removal therefrom and for feeding or watering.

(i)(1) *Horses and cattle.* Rump boards in pens for horses or cattle shall form a solid wall at least 4 feet high for cattle and 4 feet 6 inches high for horses and shall be of lumber not less than 1½ inches thick if tongued and grooved or 2 inches thick if square edged or of plywood of the same strength. Where the deck is clear of obstructions, rump boards may be set on the inside of the rail stanchions. When this is not possible, sections so affected may be brought forward to clear such obstructions and shall be fastened by stanchions provided for this purpose. On lower decks where the ship's construction so justifies, rump boards may be affixed to 2" x 6" wooden pieces set the same as prescribed for stanchions. Rump boards may be formed by filling spaces between cargo battens. Rump boards in stalls or pens built alongside hatches need be carried down only to the coaming line.

(2) *Sheep, goats, and swine.* Pens for sheep, goats, and swine on all exposed decks shall be provided with rump boards of the specified size built to a height of 2 feet 6 inches.

(j)(1) *Horses and cattle.* Division boards in pens for horses and cattle shall be used to separate all stalls and pens and to close the sides thereof at the ends of rows. They shall be used in sets of four boards of 2" x 10" dressed lumber separated by 3 inch spacers, shall extend from the rump boards to the inboard stanchions, and shall be fitted into appropriate channels or slots at both ends in a manner that will permit their ready removal.

(2) *Sheep, goats, and swine.* Division boards and those forming ends of pens for sheep, goats, and swine shall be the same as prescribed for rump boards for these animals in paragraph (i) of this section.

[45 FR 28990, June 7, 1977. Redesignated at 45 FR 86413, Dec. 31, 1980]

§ 91.29 Hatches.

(a) Animals may be placed on hatches on exposed decks on an ocean vessel if the pens or stalls are securely lashed down.

(b) Animals may be placed on hatches on underdecks on an ocean vessel provided the height requirements of § 91.25 (e) and (f) are met and sufficient space shall be left clear on such hatches for passageway across ship.

(c) On all hatches on which animals are carried and under which hay and feed or animals are stowed, sufficient space shall be left clear for the proper removal and handling of such hay and feed and animal carcasses. Such hatches shall be watertight.

[42 FR 28990, June 7, 1977. Redesignated at 45 FR 86413, Dec. 31, 1980]

§ 91.30 Defective fittings.

If previously used fittings aboard an ocean vessel are employed, any portion thereof found by the inspector to be worn, decayed, unsound, or otherwise defective shall be replaced.

[42 FR 28990, June 7, 1977. Redesignated at 45 FR 86413, Dec. 31, 1980]

PART 92—IMPORTATION OF CERTAIN ANIMALS AND POULTRY AND CERTAIN ANIMAL AND POULTRY PRODUCTS; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCE AND SHIPPING CONTAINERS THEREON

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AUTHORITY: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102-105, 111, 134a, 134b, 134c, 134d, 134f, and 135; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 28 FR 5971, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

GENERAL PROVISIONS

§ 92.1 Definitions.

Whenever in this part of the following terms are used unless the context otherwise requires, they shall be construed, respectively, to mean:

(a) *Department.* The United States Department of Agriculture.

(b) *Veterinary Services.* The Veterinary Services unit of the Department.

(c) *Deputy Administrator, Veterinary Services.* The Deputy Administrator, Veterinary Services, or any official in the Veterinary Services unit of the Animal and Plant Health Inspection Service of the Department to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(d) *Inspector.* An inspector of the Veterinary Services.

(e) *Animals.* Cattle, sheep, goats, other ruminants, swine, horses, asses, mules, zebras, dogs, and poultry.

(f) *Cattle.* Animals of the bovine species.

(g) *Ruminants.* All animals which chew the cud, such as cattle, buffaloes, sheep, goats, deer, antelopes, camels, llamas and giraffes.

(h) *Swine.* The domestic hog and all varieties of wild hogs.

(i) *Horses.* Horses, asses, mules, and zebras.

(j) (1) *Poultry.* Chickens, ducks, geese, swans, turkeys, doves, pheasants, grouse, partridges, quail, guinea fowl, and pea fowl, of all ages, including eggs for hatching.

(2) *Birds.* All members of the class *aves* (including eggs for hatching), other than poultry or pigeons.

(i) *Pet birds.* Birds which are imported for the personal pleasure of their individual owners and are not intended for resale.

(ii) *Commercial birds.* Birds which are imported for resale, breeding, public display, or any other purpose, except pet birds, zoological birds, research birds, or performing or theatrical birds.

(iii) *Zoological birds.* Birds intended for breeding or public display, for recreational or educational purposes, at a zoological park.

(iv) *Research birds.* Birds which are to be used for research purposes only.

(v) *Performing or theatrical birds and poultry.* Birds and poultry which are to be used in shows, theatrical acts or performances only.

(vi) *Smuggled birds.* Any bird which has been brought into the United States contrary to any Federal law or regulation and which has been seized by any official of any Department of the United States Government or which has been abandoned to the United States.

(3) *Pigeons.* All species of pigeons.

(k) *Accredited areas.* Areas in Canada in which the percentage of cattle infected with tuberculosis is officially declared by the Canadian Government to be less than one-half of 1 percent.

(l) *Restricted areas.* Areas in Canada that are in process of becoming accredited as defined in paragraph (k) of this section.

(m) *Recognized slaughtering establishment.*[1] An establishment where slaughtering operations are regularly carried on under Federal or State inspection and which has been approved by Veterinary Services to receive animals for slaughter under this Part.

(n) *Immediate slaughter.* Consignment directly from the port of entry to a recognized slaughtering establishment[1] and slaughter thereat within two weeks from the date of entry.

(o) *Communicable disease.* Any contagious, infectious, or communicable disease of domestic livestock, poultry or other animals.

(p) *Fever tick.* Boophilus annulatus, including, but not limited to, the varieties Americana and Australia.

(q) *Permitted dip.* A dip permitted by the Division to be used in the official dipping of cattle and horses for fever ticks and for dipping cattle and sheep for scabies.

(r) *Brucellosis certified free herd.* A herd in which all eligible cattle in the herd were negative to brucellosis tests under the Canadian requirements and which is officially certified by the Canadian Government as a brucellosis free listed herd.

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[1] The name of recognized slaughtering establishments approved under this Part may be obtained from the Area Veterinarian in Charge, Veterinary Services, for the State of destination of the shipment.

(s) *Western provinces of Canada.* Manitoba, Saskatchewan, Alberta and British Columbia.

(t) *Zoological park.* A professionally operated zoo, park, garden or other place, maintained under the constant surveillance of a Doctor of Veterinary Medicine, for the exhibition of live animals, pigeons or birds, for the purpose of public recreation or education.

(u) *Weanling or yearling.* Any horse, weaned from its dam, which was foaled not more than 731 days prior to its offer for entry into the United States.

(v) *Port veterinarian.* A veterinarian employed by Veterinary Services to perform duties required under this part at a port of entry.

(w) *Brucellosis certified free provinces of Canada.* Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland (including Labrador), Nova Scotia, Prince Edward Island, and Saskatchewan, known in Canada as brucellosis accredited free provinces.

(x) *Herd.* Any group of animals maintained on common ground for any purpose, or two or more groups of animals of the same species under common ownership or supervision, which are geographically separated, but among which there is an interchange or movement of animals without regard to health status.

(y) *Persons.* Any individual, corporation, company, association, firm, partnership, society or joint stock company.

(z) *Operator.* For the purposes of § 92.11, any person operating an approved quarantine facility.

(aa) *Accredited veterinarian.* A veterinarian approved by the Deputy Administrator in accordance with the provisions of Part 161 of this title to perform functions specified in Parts 1, 2, 3, and 11 of Subchapter A, and Subchapters B, C, and D of this chapter, and to perform functions required by cooperative State-Federal disease control and eradication programs.

(bb) *Licensed veterinarian.* Any person licensed by any country or political subdivision thereof to practice veterinary medicine.

[28 FR 5971, June 13, 1963, as amended at 37 FR 9019, May 4, 1972; 37 FR 17465, Aug. 29, 1972; 38 FR 8240, Mar. 30, 1973; 39 FR 16853, May 10, 1974; 40 FR 33650, Aug. 11, 1975; 42 FR 49441, Sept. 21, 1977; 45 FR 2839, Jan. 15, 1980; 45 FR 36358, May 30, 1980; 46 FR 26041, May 11, 1981; 46 FR 50935, Oct. 16, 1981; 47 FR 594, Jan. 6, 1982; 50 FR 30413, July 26, 1985]

§ 92.2 General prohibitions; exceptions.

(a) No animal or product or bird subject to the provisions of this part shall be brought into the United States except in accordance with the regulations in this part and Part 94 of this subchapter;[1] nor shall any such animal or product or bird be handled or moved after physical entry into the United States before final release from quarantine or any other form of governmental detention except in compliance with such regulations: *Provided,* That, except as prohibited by section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), the Deputy Administrator may upon request in specific cases permit animals or products or birds to be brought into or through the United States under such conditions as he may prescribe, when he determines in the specific case that such action will not endanger the livestock or poultry of the United States.

(b) In order to protect the poultry industry of the United States from exotic Newcastle disease and other communicable diseases of poultry, the importation of birds into the United States is prohibited, except as provided in paragraphs (a), (c), (d), (f), or (j) of this section, and except that birds from Canada may either be imported under the provisions of this section or under the provisions applicable to importation of poultry from Canada as specified in § 92.5(b), § 92.19 and § 92.26.

(c)(1) Pet birds offered for entry from Canada and which are not known to be affected with or exposed to any communicable disease of poultry, which are caged (prior to release from the port of entry) and which are personal pets, may be imported by the owner thereof at any port of entry designated in § 92.3[2a]: *Provided,* That, such birds are found upon port of entry veterinary inspection under § 92.8 to be free of poultry diseases and at the time of entry the owner signs and furnishes to the Deputy Administrator, Veterinary Services, a statement stating that the bird or birds have been in his possession for a minimum of 90 days preceding the date of importation and that during such time such birds have not been in contact with poultry or other birds (for example, association with other avian species at exhibitions or in aviaries).

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[1] Importations of certain animals from various countries are absolutely prohibited under Part 94 because of specified diseases.

(2)(i) Pet birds which originated in the United States and have not been outside the country for more than 60 days may be offered for entry under the provisions of § 92.2(c)(1)[2a]: *Provided,* That such birds are also accompanied by a United States veterinary health certificate issued prior to the departure of the birds from the United States and the certificate shows the leg band or tattoo number affixed to the birds prior to departure: *And provided further,* That during port of entry veterinary inspection it is determined that the leg band or tattoo on the bird is the same as the one listed on the health certificate.

(ii) Lots of pet birds of United States origin which have been outside the United States for more than 60 days which are found upon port of entry veterinary inspection to be free of poultry diseases, and that otherwise meet the requirements of paragraph (c)(2)(i) of this section, may be imported by the owner thereof if, the owner importing such birds signs and furnishes to the Deputy Administrator, Veterinary Services, the following:

(A) A notarized declaration under oath or affirmation (or a statement signed by the owner and witnessed by a Department inspector) stating that the bird or birds have not been in contact with poultry or other birds while out of the country (For example, association with other avian species at exhibitions or at aviaries); and

(B) An agreement on VS Form 17-8, obtainable from a Federal inspector at the port of entry, stating (*1*) that the birds will be maintained in confinement in his personal possession separate and apart from all poultry and other birds for a minimum of 30 days following importation at the address where the birds are to be held and made available for health inspection and testing by Department inspectors upon request until released at the end of such period by such an inspector and (*2*) that appropriate Federal officials in the State of destination will be immediately notified if any signs of disease are noted in any of the birds or any bird dies during that period. The owner importing such birds must comply with the provisions of the aforementioned agreement before the birds may be released from confinement. Lots of pet birds of United States origin which do not otherwise meet the requirements of paragraphs (c)(1) or (c)(2) of this section may be offered for entry under the provisions of paragraph (c)(3) of this section.

(3) Pet birds which are not known to be affected with or exposed to communicable diseases of poultry may be offered for entry at one of the ports of entry designated in § 92.3(f) under the following conditions:[2a]

(i) The pet birds shall be accompanied by a veterinary health certificate issued by a national government veterinary officer of the country of export stating that he personally inspected the birds listed on the health certificate and found them to be free of evidence of Newcastle disease, ornithosis, and other communicable diseases of poultry, and that the birds were being exported in compliance with the laws and regulations of the country of export. Certificates in a foreign language must be translated into English at the expense of the importer.

(ii) An advanced reservation fee as required by § 92.4(a)(4) and a request for space which has been confirmed in writing, at a USDA-operated quarantine facility shall be made with the port veterinarian[3] at the port where the birds are to be held for a minimum 30-day isolation in a biologically secure unit separate and apart from all other avian species, except, that birds arriving without an advanced reservation may be handled if an isolation unit is available, provided the reservation fee as required in § 92.4(a)(4) is paid. Pet birds offered for entry at a port of entry that has not been designated as provided, in § 92.3, or pet birds arriving without an advanced reservation at a port of entry designated in § 92.3 but at which isolation units are not available, shall be refused entry at such port. However, such pet birds may be transported at the owner's expense to another port of entry designated in § 92.3 if available quarantine space exists, if the reservation fee is paid and the birds are shipped to such other port under conditions deemed sufficient by the Deputy Administrator to prevent the spread of communicable diseases of poultry: *Provided*, That pet birds arriving with or without an advance reservation at the port of Hidalgo, Texas, will be transported at Department expense to the quarantine facility at Mission, Texas, if available quarantine space exists at that facility, until quarantine facilities are available at Hidalgo, Texas; and pet birds arriving with or without an approved reservation entered at the port of New York, New York, will be transported at Department expense to the quarantine facility at Newberg, New York, if available quarantine space exists at the facility, until quarantine facilities are available at New York, New York. Following the isolation period, if such birds are found to be free from communicable diseases of poultry, the birds shall be returned at Department expense to the respective ports of Hidalgo, Texas, or New York, New York, as appropriate, for Agriculture release for entry through U.S. Customs.

[2a] U.S. Public Health Service Regulations (42 CFR 71.164(e)) restrict the entry of pet psittacine birds to two birds per family per year.

(iii) During the isolation period, the birds shall be subjected to such tests and procedures as required by the Deputy Administrator to determine whether the birds are free from communicable diseases of poultry.

(iv) Following the isolation period, if the birds are found to be free of communicable disease of poultry, the port veterinarian shall issue an agriculture release for entry through U.S. Customs. If the birds are found during port of entry inspection or during quarantine to be infected with or exposed to a communicable disease of poultry, such birds shall be refused entry and handled in accordance with § 92.11(e) of this part.

(v) The owner of the birds is responsible for all costs which result from these procedures and shall reimburse Veterinary Services for governmental expenses in accordance with § 92.12 (b) and (c) of this part.

(d) Except for animals prohibited entry by section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), the provisions in this Part 92 relating to animals and birds shall not apply to healthy animals (other than poultry) in transit through the United States if they are not known to be infected with or exposed, within the 60 days preceding the date of export from the country of origin, to communicable diseases of such animals, or to healthy poultry or birds not known to be infected with or exposed, within the 90 days preceding the date of export from the country of origin, to communicable diseases of poultry, if an import permit[4] has been obtained under § 92.4 of this Chapter and all conditions therein are observed; and if such animals or birds are handled as follows:

(1) (i) They are maintained under continuous confinement in transit through the United States aboard an aircraft, ocean vessel, or other means of conveyance; or

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[3] The names and addresses of the port veterinarians, as well as a fee schedule for quarantine charges, are available from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Hyattsville, Maryland 20782.

[4] Such permit may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, Hyattsville, Maryland 20782. Requests for approval of such facilities should also be made to the Deputy Administrator.

(ii) They are unloaded, in the course of such transit, into an animal or bird holding facility which is provided by the carrier or its agent and has been approved[4] in advance by the Deputy Administrator in accordance with paragraph (d)(3) of this section as adequate to prevent the spread within the United States of any livestock or poultry disease, and they are maintained there under continuous confinement until loaded aboard a means of conveyance for transportation from the United States and are maintained under continuous confinement aboard such means of conveyance until it leaves the United States; the import permit will specify any additional conditions necessary to assure that the transit of the animals or birds through the United States can be made without endangering the livestock or poultry of the United States, and that Department inspectors may inspect the animals or birds on board such means of conveyance or in such holding facility as provided in section 5 of the Act of July 2, 1962 (21 U.S.C. 134d) to ascertain whether the requirements of this paragraph are met, and dispose of them in accordance with section 2 of the Act of July 2, 1962 (21 U.S.C. 134a) if such conditions are not met; and

(2) The carrier or its agent executes and furnishes to the collector of Customs at the first port of arrival a declaration stating that the animals or birds will be retained aboard such means of conveyance or in an approved holding facility during transshipment as required by this paragraph.

(3) Provisions for the approval of facilities required in this paragraph are:

(i) They must be sufficiently isolated to prevent direct or indirect contact with all other animals and birds while in the United States.

(ii) They must be so constructed that they provide adequate protection against environmental conditions and can be adequately cleaned, washed and disinfected.

(iii) They must provide for disposal of animals and bird carcasses, manure, bedding, waste and any related shipping materials in a manner that will prevent dissemination of disease.

(iv) They must have provisions for adequate sources of feed and water and for attendants for the care and feeding of animals and birds in the facility.

(v) They must comply with additional requirements as may be imposed by the Deputy Administrator if deemed applicable for a particular shipment.

(vi) They must also comply with all applicable local, State and Federal requirements for environmental quality and with the provisions of the Animal Welfare Regulations in Chapter I of this Title, as applicable.

(e) All of the provisions of this Part 92 shall apply to pigeons to the same extent and in the same manner as they apply to poultry.

(f) Commercial birds, zoological birds, research birds, or pet birds may be imported into the United States if they meet the requirements of §§ 92.3(f), 92.4, 92.5(c), 92.8(b), and 92.11(e) which specifically apply to such birds and the requirements of all other sections in this part that are applicable to poultry or to animals generally.

(g) Performing or theatrical birds and performing or theatrical poultry may be imported at any of the ports of entry listed in § 92.3 if accompanied by an import permit as required by § 92.4 and such birds or poultry are found upon port of entry veterinary inspection to be free of communicable diseases of poultry.

(h) The provisions in this part relating to poultry shall not be applicable to performing or theatrical poultry; however, the provisions in this part applicable to performing or theatrical birds shall be applicable to performing or theatrical poultry.

(i)(1) Except as provided in paragraph (i)(2) of this section notwithstanding the other provisions of this part concerning the importation of horses into the United States, the importation of all horses from the following listed countries and the importation of all horses which have been in any such country within the 12 months immediately preceding their export to the United States is prohibited because of the existence of CEM in such countries: Austria, Belgium, Denmark, Ireland, Italy, Japan, Federal Republic of Germany, France, Sweden, and the United Kingdom (England, Scotland, Northern Ireland, Wales and the Isle of Man).

(2) The provisions of paragraph (i)(1) of this section shall not apply to the following:

(i) Horses imported in accordance with conditions prescribed by the Deputy Administrator as provided in § 92.2(a).

(ii) Geldings, weanlings, or yearlings whose age is certified on the import health certificate prescribed in § 92.17.

(iii) Thoroughbred horses imported for permanent entry from the Federal RepublK c of Germany, the United Kingdom, Ireland, and France, if such horses are accompanied at the time of importation by import permits in accordance with § 92.4 of the regulations and are accompanied by a certificate issued and signed by a veterinarian who is qualified to issue such certificate by the foreign country from which the horses are exported. This certificate shall be endorsed by an official of the National Veterinary Service of the country of export who certifies that the veterinarian signing and issuing the certificate is qualified to do so. The veterinarian signing and issuing the certificate shall certify that:

(A) He/she has examined the daily records of the horse's activities maintained by the trainer and certified to be current, true and factual by the veterinarian in charge of the training or racing stable, and examined the records of the horse's activities maintained by a record-keeping association which has been specifically approved by Veterinary Services,[44] and certified by such association to be current and true and factual, for the following information: identification of the horse by name, sex, age, breed, and all identifying marks, identify all premises where the horse has been since reaching 731 days of age and the dates that the horse was at such premises, and that none of the premises are breeding premises. Further, that he/she has compared the records maintained by the approved recordkeeping association with the records kept by the trainer and has found the information described above on these two sets of records to be consistent and current.

(B) For female horses over 731 days of age, that negative cultures for CEM were conducted from one set of specimens collected during estrus consisting of one specimen from the endometrium, one specimen from the mucosal surface of the urethra, one specimen from the mucosal surface of the clitoral fossa, and one specimen from the mucosal surface of the cervix, and that negative cultures for CEM were conducted from two additional sets of specimens consisting of one specimen from the mucosal surface of the urethra, one specimen from the mucosal surface of the clitoral fossa, and one specimen from the mucosal surface of the cervix; that the sets of specimens were collected at intervals of no less than 7 days; and that the last of these sets of specimens was collected within 30 days of exportation.

(C) For stallions over 731 days of age, that three negative cultures were conducted from specimens collected from each of the surfaces of the urethral fossa, the urethra, and the penile sheath for each culture at intervals of no less than 7 days, and that the last of the sets of specimens was collected within 30 days of the date of exportation; and

(D) At the time each specimen for culturing is taken, a licensed veterinarian of such country has clinically examined such horses and has certified that such horses are clinically free of evidence of CEM. All specimens shall be cultured in a laboratory approved by the National Veterinary Service of such country to conduct cultures for CEM.

(iv) Any stallion over 731 days of age imported for permanent entry, if accompanied by an import permit as required in § 92.4 of the regulations and if such stallion is accompanied by a certificate which contains the information required by § 92.17, is either signed by a salaried veterinarian of the National Veterinary Services of the country of origin or signed by a veterinarian authorized by the National Veterinary Services of the country of origin and endorsed by a salaried veterinarian of the National Veterinary Services of the country of origin, thereby representing that the veterinarian signing the certificate was authorized to do so, and, in addition, states that:

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[44] The following breed associations and their record systems have been approved by the Department: Weatherby's Ltd. for the United Kingdom and Ireland; Haras du Pain for France; Direktorium Fur Vollblutzucht und Rennen e.v. for the Federal Republic of Germany; and the Australian Trotting Council and the affiliated State Trotting Control Boards for Australia.

(A) On 5 consecutive days the prepuce, penis, including the fossa glandis, and urethral sinus of the stallion described on the certificate were aseptically cleaned and washed (scrubbed) while in full erection with a solution of not less than 2 percent of a surgical type of chlorhexidine and were then thoroughly coated (packed) with an ointment of not less than 0.2 percent nitrofurazone under the supervision of the veterinarian signing the certificate;

(B) After an interim of 7 days following the fifth consecutive day of scrubbing and packing required in paragraph (i)(2)(A) of this section, three separate sets of three specimens each were collected from the stallion described on the certificate, at intervals of not less than 7 days between the collection of each set, from the surface of the fossa glandis, urethral sinus and the penile sheath respectively, under the supervision of the veterinarian signing the certificate and that all of the 9 specimens collected were cultured negative for CEM in a laboratory approved to culture for CEM by the National Veterinary Service of the country of origin;

(C) The last of the three sets of specimens collected in paragraph (i)(2)(iv)(B) was collected and cultured negative within 30 days of the date of export of the stallion described on the certificate; and

(D) The stallion described on the certificate was not used for natural or artificial insemination breeding from the time the 5 consecutive days of scrubbing and packing procedure was begun through the date of export.

(v) Any mare over 731 days of age imported, if:

(A)(*1*) The mare is accompanied by an import permit as required in § 92.4, and

(*2*) The mare is accompanied by a certificate, which contains the information required by § 92.17, is either signed by a salaried veterinarian of the National Veterinary Services of the country of origin or signed by a veterinarian authorized by the National Veterinary Services of the country of origin and endorsed by a salaried veterinarian of the National Veterinary Services of the country of origin, thereby representing that the veterinarian signing the certificate was authorized to do so, and, in addition, states:

(*i*) That the veterinarian signing the certificate directly supervised the surgery, topical treatment and specimen collection required by paragraphs (i)(2)(v)(B), (i)(2)(v)(C), (i)(2)(v)(D), (i)(2)(v)(E) and (i)(2)(v)(G) of this section.

(*ii*) The dates on which the surgery, treatment and cultures required by paragraphs (i)(2)(v)(B), (i)(2)(v)(C), (i)(2)(v)(D), (i)(2)(v)(E), and (i)(2)(v)(G) of this section were performed.

(*iii*) The results of all cultures required by paragraph (i)(2)(v) of this section and the name of the laboratory that conducted such cultures.

(*iv*) That, except as provided in paragraph (i)(2)(v)(E) of this section, all specimens required to be cultured have been found negative for CEM; and

(B) A licensed veterinarian collects a specimen from the clitoral sinus of the mare within 2 hours prior to surgery required by paragraph (i)(2)(v)(C) of this section, and submits such specimen to a laboratory approved to culture for CEM by the National Veterinary Service of the country of origin; and

(C) A licensed veterinarian surgically removes the clitoral sinuses of the mare and submits such clitoral sinuses to a laboratory approved to culture for CEM by the National Veterinary Service of the country of origin; and

(D) For 5 consecutive days, beginning the 7th day after removal of the clitoral sinuses, a licensed veterinarian aseptically cleans and washes (scrubs) the external genitalia and vaginal vestibule, including the clitoral fossa with a solution of not less than 2 percent chlorhexidine in a detergent base and then fills the clitoral fossa and coats the external genitalia and vaginal vestibule with an ointment of not less than 0.2 percent nitrofurozone; and

(E) After an interim of 7 days following the 5th consecutive day of scrubbing the external genitalia and the vaginal vestibule and filling the clitoral fossa, a licensed veterinarian collects 3 separate specimens from the clitoral fossa, at an interval of not less than 7 days between the collection of each specimen, and each specimen is cultured with negative results for CEM at a laboratory approved to culture for CEM by the National Veterinary Service of the country of origin. For any nonpregnant mare, a licensed veterinarian collects an additional specimen during estrus from the endometrium of the uterus and the specimen is cultured with negative results for CEM at a laboratory approved to culture for CEM by the National Veterinary Service of the country of origin. The last of the 3 sets of specimens collected during this procedure is collected within 30 days of the date of export of the mare described on the certificate; and

(F) The mare described on the certificate is not bred from the time treatment required by this paragraph was begun through the date of export; and

(G) Any specimen required by paragraph (i)(2)(v)(B), (i)(2)(v)(C), (i)(2)(v)(D), or (i)(2)(v)(E) of this section is found to be positive for CEM, and a licensed veterinarian collects 3 additional separate sets of specimens from the clitoral fossa at not less than 7 day intervals, with the first set collected not less than 1 year from the date of the last positive culture and each additional specimen is cultured with negative results at a laboratory approved to culture for CEM by the National Veterinary Services of the country of origin. One set shall be collected from the endometrium of the uterus during estrus and the last set shall be collected within 30 days prior to the date of export.

(H) Any mare subject to the provisions of § 92.2(i)(2)(v) which is found upon examination during preentry quarantine to have had an incomplete clitoral sinusectomy, but which is otherwise eligible for entry, may, at the option and expense of the importer, be moved to the School of Veterinary Medicine, Cornell University, Ithaca, New York, or to the College of Veterinary Medicine, University of California, Davis, California, where the surgery required to qualify such mare for importation may be performed by a licensed veterinarian mutually acceptable to the importer, the University, and the Department. Within two hours prior to such surgery, a licensed veterinarian shall collect a specimen from the clitoral sinus of the mare, and this sample, together with the clitoral sinuses or portion thereof removed, shall be submitted to a State or Federal animal disease diagnostic laboratory for culture. Following surgery and inspection by a Veterinary Services inspector for complete removal of the clitoral sinuses, such mare must be moved to the State of destination shown on the permit as soon as it is possible to do so without endangering the mare. Upon arrival in the State of destination, the mare will be handled in the same manner as if the surgery had been performed in the country of origin.

(vi) Horses which have been temporarily exported from the United States to any country listed in paragraph (i)(1) of this section for a period not to exceed 60 days and have not been bred to any animal during the 60-day period are eligible for return to the United States without meeting the requirements of paragraph (i)(2)(iv) of this section if:

(A) They are accompanied at the time of entry and inspection at the port of entry by:

(*1*) A copy of the United States health certificate issued for the exportation of the horse from the United States and endorsed in accordance with the export regulations in Part 91 of this chapter;

(*2*) An import permit issued in accordance with § 92.4 of the regulations in this Part at the time of exportation;

(*3*) A certificate that, in each CEM-affected country which the horses have entered since their departure from the United States, has been either signed by a salaried veterinarian of the national veterinary services of such country *or* signed by a veterinarian authorized by the national veterinary services of such country and endorsed by a salaried veterinarian of the national veterinary services of such country (the endorsement representing that the veterinarian signing the certificate was authorized to do so), and stating that during the time they were in each such country:

(*i*) The horses have been held separate and apart from all other horses except for the time they were actually participating in an event or were being exercised by their trainers;

(*ii*) The premises on which such horses were held were not used for any equine or horse breeding purpose;

(*iii*) That the horses were not bred nor had any other sexual contact or genital examination while in such country; and

(*iv*) That all transport while in such country was carried out in cleaned and disinfected vehicles in which no other horses were transported since such cleaning and disinfection.

(B) They are examined by a Veterinary Services inspector at the United States port of entry and are determined by him to be the identical animals covered by the health certificate, the import permit and the certificate signed by the appropriate salaried veterinarian of the foreign country, and are determined by the inspector to be free of communicable disease and exposure thereto; and

(C) They are quarantined and tested at the port of entry as provided in § 92.11(d) of this part prior to release.

(j) Any smuggled bird shall:

(1) Be refused entry into the United States and be removed from the United States,[15] or

(2) Be quarantined in a Veterinary Services quarantine facility pending negative results to two consecutive tests for velogenic viscerotropic Newcastle disease (VVND)[16] administered not less than 30 days apart, with the first test administered within seven days after the bird enters the facility.

Tissue samples from any smuggled bird which has died prior to release from quarantine shall be submitted for VVND isolation. Smuggled birds shall also be subject to such other tests and procedures to determine whether the birds are free from communicable diseases of poultry other than VVND when the port veterinarian determines that the bird in question has shown physical symptoms of being affected with or exposed to communicable diseases of poultry. A lot of smuggled birds placed into the quarantine facility shall be handled on an "all-in, all-out" basis: *Provided,* That birds of endangered and threatened species, as determined by the Department of Interior (16 U.S.C. 1533, as amended) shall be separated for quarantine and testing as separate lots. If VVND or any other communicable disease of poultry is diagnosed in any smuggled bird at any point or if it is determined that any smuggled bird has been exposed to VVND or any other such communicable disease, such birds shall not be released from quarantine and shall be disposed of in accordance with procedures established by the Deputy Administrator to prevent the entry of communicable diseases of livestock or poultry into the United States. However, if endangered or threatened species are determined to be exposed such birds shall be held in permanent quarantine in accordance with such conditions as the Deputy Administrator may prescribe to protect poultry of the United States. At the time any smuggled bird enters the quarantine facility, it shall be identified in a manner approved by the Deputy Administrator, Veterinary Services.

If the laboratory tests for VVND are negative and as determined by the port veterinarian the birds are free of clinical evidence of diseases of poultry at the end of the quarantine period, the port veterinarian shall issue an agricultural release for entry of the birds through the United States Customs Service at the termination of the quarantine period. Providing that the sale of the smuggled birds is not contrary to any Federal law or regulation, expenses incurred by the Department for the handling of the smuggled birds under this paragraph shall be reimbursed from funds derived from the sale or disposition of the smuggled birds after their release from quarantine. Any smuggled bird which by law may not be sold, or so disposed, shall be quarantined in accordance with such procedures as the Deputy Administrator may establish to prevent the introduction of communicable diseases of livestock or poultry into the United States, in accordance with the law.

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[15] Birds that would require handfeeding will be refused entry.

[16] Such tests are conducted according to the Protocol for VVND which is available upon request from the Deputy Administrator.

(Approved by the Office of Management and Budget under control number 0579-0069)

[37 FR 17465, Aug. 29, 1972]

EDITORIAL NOTE: For Federal Register citations affecting § 92.2, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 92.2a Inspection of certain aircraft and other means of conveyance and shipping containers thereon; unloading, cleaning, and disinfection requirements.

(a) *Inspection*: All aircraft and other means of conveyance (including shipping containers thereon) moving into the United States from any foreign country are subject to inspection without a warrant by properly identified and designated inspectors of the Division to determine whether they are carrying any animal, carcass, product or article regulated or subject to disposal under any law or regulation administered by the Secretary of Agriculture for prevention of the introduction or dissemination of any communicable animal disease (21 U.S.C. 134d).

(b) *Unloading requirements*: Whenever in the course of any such inspection at any port in the United States the inspector has reason to believe that the means of conveyance or container is contaminated with material of animal (including poultry) origin, such as, but not limited to, meat, organs, glands, extracts, secretions, fat, bones, blood, lymph, urine, or manure, so as to present a danger of the spread of any communicable animal disease, the inspector may require the unloading of the means of conveyance and the emptying of the container if he deems it necessary to enable him to determine whether the means of conveyance or container is in fact so contaminated. The principal operator of the means of conveyance and his agent in charge of the means of conveyance shall comply with any such requirement under the immediate supervision of, and in the time and manner prescribed by, the inspector.

(c) *Cleaning and disinfection*: Whenever, upon inspection under this section, an inspector determines that a means of conveyance or shipping container is contaminated with material of animal origin so as to present a danger of the spread of any communicable animal disease, he shall notify the principal operator of the means of conveyance or his agent in charge, of such determination and the requirements under this section. The person so notified shall cause the cleaning and disinfection of such means of conveyance and container under the immediate supervision of, and in the time and manner prescribed by, the inspector.

(d) For purposes of this section, the term "shipping container" means any container of a type specially adapted for use in transporting any article on the means of conveyance involved.

[32 FR 15707, Nov. 15, 1967]

§ 92.3 Ports designated for the importation of animals and birds.

(a) *Air and ocean ports.* The following ports have Veterinary Services inspection and quarantine facilities necessary for quarantine stations and all animals shall be entered into the United States through these stations, except as provided in paragraphs (b), (c), (d), (e), (g), and (h) of this section, §§ 92.11(d) and 92.24: Los Angeles, California (quarantine space at Los Angeles will be allowed on a priority basis for horses entering the United States for participation in the 1984 Olympics); Miami, Florida; Honolulu, Hawaii; and Newburgh, New York.

(b) *Canadian border ports.* (1) The following land border ports are designated as having the necessary inspection facilities for the entry of animals from Canada: Houlton and Jackman, Maine; Derby Line and Highgate

Springs, Vermont; Champlain, Ogdensburg, Rooseveltown, Alexandria Bay, and Buffalo, New York; Detroit, Port Huron and Sault Ste. Marie, Michigan; Pembina, Portal, and Dunseith, North Dakota; Raymond, Opheim and Sweetgrass, Montana; Eastport, Idaho; Oroville, Sumas, Blaine, and Lynden, Washington.

(2) International Falls, Minnesota, is designated as a port of entry for horses from Canada.

(c) *Mexican border ports.* The following land border ports are designated as having the necessary inspection facilities for the entry of animals from Mexico: Brownsville, Hidalgo, Laredo, Eagle Pass, Del Rio, Presidio, and El Paso, Texas; Douglas, Naco, Nogales, Sasabe, and San Luis, Arizona; Calexico and San Ysidro, California; and Antelope Wells, and Columbus, New Mexico.

(d) *Special ports.* Charlotte Amalie, St. Thomas, and Christiansted, St. Croix, in the United States Virgin Islands, are hereby designated as quarantine stations for the entry of ruminants and swine from the British Virgin Islands into the United States Virgin Islands for immediate slaughter.

(e) *Limited ports.* The following ports are designated as having inspection facilities for the entry of animals and animal products such as animal semen, animal test specimens, or hatching eggs and day old chicks which do not appear to require restraint and holding inspection facilities:

Anchorage, Alaska; San Diego, California; Denver, Colorado; Jacksonville, St. Petersburg-Clearwater, and Tampa, Florida; Chicago, Illinois; New Orleans, Louisiana; Portland, Maine; Baltimore, Maryland; Boston, Massachusetts, Minneapolis, Minnesota; Great Falls, Montana; Portland, Oregon; San Juan, Puerto Rico; Galveston and Houston, Texas; and Seattle, Spokane, and Tacoma, Washington.

(f) *Special ports for pet birds.* New York, New York; Miami, Florida; Laredo, El Paso, and Hildalgo, Texas; Nogales, Arizona; San Ysidro and Los Angeles, California; and Honolulu, Hawaii, are designated as ports of entry for pet birds imported under the provisions of § 92.2(c)(3).

(g) *Ports and quarantine facilities provided by the importer for horses.* Horses, except horses from or which have transited any country in which African horsesickness is declared to exist,[a] may be entered into the United States at any port specified in paragraph (a) of this section, or at any other port designated as an international port or airport by the U.S. Customs Service and quarantined at quarantine facilities provided by the importer provided that applicable provisions of §§ 92.2(i), 92.4(a), 92.8(a), 92.11(d), and 92.17 are met.

(h) *Designation of other ports.* The Secretary of the Treasury has approved the designation as quarantine stations of the ports specified in this section. In special cases other ports may be designated as quarantine stations under this section by the Deputy Administrator, Veterinary Services with the concurrence of the Secretary of the Treasury.

(i) Notwithstanding any other provisions of this section, all commercial birds, zoological birds, or research birds shall be imported only at a port of entry specified in § 92.8(b).

[28 FR 5971, June 13, 1963, as amended at 40 FR 33650, Aug. 11, 1975; 44 FR 42672, July 20, 1979; 45 FR 11796, Feb. 22, 1980; 45 FR 52775, Aug. 8, 1980; 47 FR 57255, Dec. 23, 1982; 48 FR 19868, May 3, 1983; 48 FR 32005, July 13, 1983; 48 FR 49001, Oct. 24, 1983; 48 FR 49500, Oct. 26, 1983; 48 FR 50064, Oct. 31, 1983; 48 FR 54469, Dec. 5, 1983; 49 FR 11824, Mar. 28, 1984; 49 FR 27138, July 2, 1984; 49 FR 27922, July 9, 1984; 49 FR 46873, Nov. 29, 1984; 50 FR 1041, Jan. 9, 1985; 50 FR 13309, Apr. 4, 1985]

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[a] Information as to the countries where African horsesickness is declared to exist may be obtained from the Deputy Administrator, Veterinary Services.

§ 92.4 Import permits for ruminants, swine, horses from countries affected with CEM, poultry, poultry semen, animal semen, birds and for animal specimens for diagnostic purposes;[1] and reservation fees for space at quarantine facilities maintained by Veterinary Services.

(a) *Application for permit; reservation required.* (1) For ruminants, swine, horses from countries listed in § 92.2(i)(1) of the regulations, horses intended for quarantine at a quarantine facility provided by the importer, poultry, poultry semen, animal semen, pet birds, commercial birds, research birds, zoological birds, and performing or theatrical birds and animal test specimens for diagnostic screening purposes, intended for importation from any part of the world, except as otherwise provided for in §§ 92.2(b) and (c), 92.19, 92.27, and 92.31, the importer shall first apply for and obtain from Veterinary Services an import permit. The application shall specify the name and address of the importer; the species, breed, number or quantity of animals, animal semen, or animal test specimens to be imported; the purpose of the importation; individual animal identification (except poultry), which includes a description of the animal, name, age, markings, if any, registration number, if any, and tattoo or eartag; the country of origin; the name and address of the exporter; the port of embarkation in the foreign country; the mode of transportation, route of travel, and the port of entry in the United States; the proposed date of arrival of the animals, animal semen, or animal test specimens to be imported; and the name of the person to whom the animals, animal semen, or animal test specimens will be delivered and the location of the place in the United States to which delivery will be made from the port of entry. Additional information may be required in the form of certificates concerning specific diseases to which the animals are susceptible, as well as vaccinations or other precautionary treatments to which the animals, animal semen, or animal test specimens have been subjected. Notice of any such requirement will be given to the applicant in each case.

(2) An application for permit to import will be denied for domestic ruminants or swine, or semen from ruminants or swine, from any country where it has been declared, under section 306 of the Act of June 17, 1930, that foot-and-mouth disease or rinderpest has been determined to exist, except as provided in paragraphs (d) and (e) of this section.

(3) An application for permit to import ruminants, swine, horses from countries listed in § 92.2(i)(1) of the regulations, horses intended for quarantine at a quarantine facility provided by the importer, poultry, poultry semen, animal semen, pet birds, commercial birds, research birds, zoological birds, and performing or theatrical birds, may also be denied because of: Communicable disease conditions in the area or country of origin, or in a country where the shipment has been or will be held or through which the shipment has been or will be transported; deficiencies in the regulatory programs for the control or eradication of animal diseases and the unavailability of veterinary services in the above mentioned countries; the importer's failure to provide satisfactory evidence concerning the origin, history, and health status of the animals or animal semen; the lack of satisfactory information necessary to determine that the importation will not be likely to transmit any communicable disease to livestock or poultry of the United States; or any other circumstances which the Deputy Administrator believes require such denial to prevent the dissemination of any communicable disease of livestock or poultry into the United States.

(4)(i) For each lot of animals or birds to be quarantined in a quarantine facility maintained by Veterinary Services, the importer or the importer's agent shall pay or ensure payment of a reservation fee of $2,500 or the amount estimated by the veterinarian in charge of the quarantine facility to be 25 percent of the cost of providing care, feed, and handling during quarantine, whichever is less; *Except* that the reservation fee shall be no less than $80.00 for each lot of birds or poultry, no less than $130.00 for each horse, and no less than $240.00 for each lot of any other animals.

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[1] For other permit requirements for birds, the regulations issued by the U.S. Department of the Interior (Part 17, Title 50, Code of Federal Regulations) and the regulations issued by the U.S. Department of Health and Human Services (Subpart J-1 of Part 71, Title 42, Code of Federal Regulations) should be consulted.

(ii) At the time the importer or the importer's agent requests a reservation of quarantine space, the importer or importer's agent shall pay the reservation fee by check or U.S. money order or ensure payment of the reservation fee by an irrevocable letter of credit from a commercial bank (the effective date on such letter of credit shall run to 30 days after the date the animals or birds are scheduled to be released from quarantine); except that anyone who issues a check to the Department for a reservation fee which is returned because of insufficient funds shall be denied any further request for reservation of a quarantine space until the outstanding amount is paid.

(iii) Any reservation fee paid by check or U.S. money order shall be applied against the expenses incurred for services received by the importer or importer's agent in connection with the quarantine for which the reservation was made. Any part of the reservation fee which remains unused after being applied against the expenses incurred for services received by the importer or the importer's agent in connection with the quarantine for which the reservation was made, shall be returned to the individual who paid the reservation fee. If the reservation fee is ensured by a letter of credit, the Department will draw against the letter of credit unless payment for services received by the importer or importer's agent in connection with the quarantine is otherwise made at least 3 days prior to the expiration date of the letter of credit.

(iv) Any reservation fee shall be forfeited if the importer or the importer's agent fails to present for entry, within 24 hours following the designated time of arrival, the horse, the lot of birds, or the lot of other animals for which the reservation was made: *Except* that a reservation fee shall not be forfeited if:

(A) Written notice of cancellation from the importer or the importer's agent is received by the office of the veterinarian in charge of the quarantine facility[2] during regular business hours (8:00 a.m. to 4:30 p.m. Monday through Friday, excluding holidays) no later than 5 days for horses or 15 days for other animals or birds prior to the beginning of the time of importation as specified in the import permit or as arranged with the veterinarian in charge of the quarantine facility if no import permit is required (the 5 or 15 day period shall not include Saturdays, Sundays, or holidays), or

(B) The Deputy Administrator, Veterinary Services, determines that services, other than provided by carriers, necessary for the importation of the animals or birds within the requested period are unavailable because of unforeseen circumstances as determined by the Deputy Administrator, Veterinary Services, (such as the closing of an airport due to inclement weather or the unavailability of the reserved space due to the extension of another quarantine).

(v) If the reservation fee was ensured by a letter of credit and the fee is to be forfeited under paragraph (a)(4)(iv) of this section, the Department will draw against the letter of credit unless the reservation fee is otherwise paid at least 3 days prior to the expiration date of the letter of credit.

(vi) When a reservation is cancelled in accordance with paragraph (a)(4)(iv)(A) of this section and the provisions of paragraph (a)(4)(iv)(B) of this section do not apply, a $40.00 cancellation fee shall be charged. If a reservation fee was paid, the cancellation fee shall be deducted from any reservation fee returned to the importer or the importer's agent. If the reservation fee was ensured by a letter of credit, the Department will draw the amount of the cancellation fee against the letter of credit unless the cancellation fee is otherwise paid at least 3 days prior to the expiration date of the letter of credit.

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[2] The addresses of USDA quarantine facilities may be found in telephone directories listing the facilities or by contacting Import-Export Animals and Products Staff, Veterinary Services, APHIS, U.S. Department of Agriculture, 6505 Belcrest Road, Hyattsville, MD 20782.

(5)(i) For stallions over 731 days of age from countries listed in § 92.2(i)(1) of the regulations and for which a permit is requested pursuant to § 92.2(i)(2)(iv) of the regultions, a permit will be issued only if the stallion for which the permit is to be issued is consigned to a State which the Deputy Administrator has approved to receive such horse in accordance with the provisions of paragraph (a)(6) of this section.

(5)(ii) The following States have been approved to receive stallions over 731 days of age pusuant to § 92.2(i)(2)(iv):

The State of California.
The State of Colorado.
The State of Kentucky.
The State of Louisiana.
The State of Maryland.
The State of New York.
The State of North Carolina.
The State of Ohio.
The State of South Carolina.
The State of Tennessee.
The State of Virginia.
The State of Wisconsin.

(6) In order to be approved to receive stallions over 731 days of age pursuant to § 92.2(i)(2)(iv) the following conditions shall be met:

(i) The State must enter into a written agreement with the Deputy Administrator, Veterinary Services, whereby the State agrees to enforce its laws and regulations to control contagious equine metritis and to abide by the conditions of approval established by the regulations in this part.

(ii)(A) The State must agree to quarantine all stallions over 731 days of age imported from countries listed in § 92.2(i)(1), pursuant to § 92.2(i)(2)(iv), until the stallions have been treated in accordance with paragraph (a)(6)(iii) of this section.

(B) The State must agree to quarantine all mares used to test stallions for CEM until the mares have been released from quarantine in accordance with paragraph (a)(6)(iii)(C)(*4*) of this section.

(iii) The State must have laws or regulations requiring that stallions over 731 days of age imported from countries listed in § 92.2(i)(1) pursuant to § 92.2(i)(2)(iv) have been treated in the following manner:

(A) One specimen each shall be taken from the prepuce, the fossa glandis, and urethral sinus of the stallion and be cultured for CEM. After the specimens have been cultured for CEM, on 5 consecutive days the prepuce, penis, including the fossa glandis, and urethral sinus of the stallion shall be thoroughly cleaned and washed (scrubbed) while in full erection with a solution of not less than 2 percent surgical scrub chlorhexidine and then thoroughly coated (packed) with an ointment of not less than 0.2 percent nitrofurazone by an accredited veterinarian under the direct supervision of a State veterinarian.

(B)(*1*) *Identification of test mares.* Mares to be used to test stallions for CEM shall be permanently identified before the mares are used for such testing with the letter "T." The marking shall be permanently applied by an inspector, State inspector, or accredited veterinarian who shall use a hot iron, freezemarking or a lip tattoo. If a hot iron or freezemarking is used, the marking shall not be less than two inches high and shall be applied to the left shoulder or left side of the neck of the mare. If a lip tattoo is used, the marking shall not be less than one inch high and three-fourths of an inch wide and shall be applied to the inside surface of the upper lip of the mare.

(*2*) After a period of seven days following the fifth consecutive day of scrubbing and packing required in paragraph (a)(6)(iii)(A) of this section, the stallion shall be bred to two mares which have not been previously used to test stallions for CEM, which are qualified prior to breeding as apparently free from CEM and which have not been bred from the time specimens were taken from the mares to qualify the mares as apparently free from CEM. To qualify as apparently free from CEM, each mare shall be tested with negative results by a complement fixation (CF) test for CEM and specimens taken from each mare shall be cultured negative for CEM.

For culture, one specimen each shall be collected during estrus from the endometrium of the uterus, clitoral sinuses and clitoral fossa. After an interval of not less than seven days, one specimen each shall be collected from the cervix, clitoral sinuses and clitoral fossa.

(C) *For mares, after breeding.* For each mare: (*1*) Three cultures for CEM shall be conducted from specimens collected from each of the mucosal surfaces of the cervix, clitoral fossa and clitoral sinuses for each culture on the second, fourth, and seventh day after the day of breeding.

(*2*) During the next estrus, specimens for culture shall be collected from the endometrium of the uterus, the clitoral sinuses and clitoral fossa. If natural estrus does not occur within 28 days of the date of the breeding, hormonal precipitation of estrus shall be carried out.

(*3*) Two blood serum samples obtained at intervals of not less than seven days between the 15th to 40th day after the day of breeding shall be tested by the complement fixation (CF) test for CEM.

(*4*) A mare which has been used to test stallions for CEM may be released from quarantine only if:

(*i*) The mare is found negative for CEM on all cultures and tests required under paragraphs (a)(6)(iii)(C)(*1*), (a)(6)(iii)(C)(*2*), and (a)(6)(iii)(C)(*3*) of this section; or

(*ii*) The mare is subjected to an ovariectomy by an accredited veterinarian under the direct supervision of a State veterinarian; or

(*iii*) The mare is treated and handled in accordance with paragraph (a)(9)(iii) of this section; or

(*iv*) The mare is moved directly to slaughter without unloading enroute, is euthanized or dies.

(D)(*1*) A stallion may be released from quarantine only if all cultures and tests of specimens from the mares used to test the stallion for CEM, are negative for CEM.

(*2*) If any culture or test required by this paragraph is positive for CEM, the stallion shall be retreated and retested in accordance with this paragraph.

(E)(*1*) All tests and cultures required by this paragraph shall be conducted at the National Veterinary Services Laboratories, Ames, Iowa, or at a laboratory approved by the Deputy Administrator, Veterinary Services, to conduct CEM cultures and tests.

(*2*) All specimens submitted to the National Veterinary Services Laboratories or an approved laboratory for CEM culture or testing shall be accompanied by a statement indicating the date and time of collection. To be eligible for CEM culture or testing the specimen must be received by the National Veterinary Services Laboratories or approved laboratory within 48 hours of collection.

(*3*) A list of laboratories approved to conduct CEM cultures and tests and the standards which must be met to attain and retain approval are available from the Deputy Administrator, Veterinary Services, APHIS, USDA, 6505 Belcrest Road, Hyattsville, Maryland 20782.

(*4*)(*i*) The Deputy Administrator, Veterinary Services, may refuse to grant approval to or may withdraw approval from a laboratory to conduct CEM cultures and tests if the Deputy Administrator, Veterinary Services, determines that the laboratory does not meet the standards necessary for approval.

(*ii*) The Deputy Administrator, Veterinary Services, shall send a written notice to an official at the laboratory which shall state the reasons for the refusal to grant approval to the laboratory to conduct CEM cultures and tests or the withdrawal of approval from the laboratory to conduct CEM cultures and tests. If there is a material dispute of fact, the laboratory shall be afforded an opportunity for a hearing with respect to the merits or validity of the refusal to grant approval to or the withdrawal of approval from the laboratory to conduct CEM cultures and tests. The hearing shall be conducted in accordance with rules of practice which shall be adopted for the hearing by the Administrator, Animal and Plant Health Inspection Service. The refusal to grant approval to or the withdrawal of approval from a laboratory to conduct CEM cultures and tests shall be effective upon service of the notification on an official of the laboratory and shall continue in effect pending the outcome of any hearing and any judicial review thereof, unless otherwise ordered by the Administrator, Animal and Plant Health Inspection Service.

(7) Approval of any State to receive stallions imported from countries affected with CEM may be suspended by the Deputy Administrator, Veterinary Services, upon his determination that any requirement of this section is not being met. After such action is taken, the animal health authorities of the approved State will be informed of the reasons for the action and afforded an opportunity to present their views thereon before such suspension is finalized; however, such withdrawal of approval shall continue in effect unless otherwise ordered by the Deputy Administrator, Veterinary Services. In those instances where there is a conflict as to the facts, a hearing shall be held to resolve such conflict.

(8)(i) For mares over 731 days of age from countries listed in § 92.2(i)(1) and for which a permit is requested pursuant to § 92.2(i)(2)(v), a permit will be issued only if the mare for which the permit is to be issued is consigned to a State which the Deputy Administrator, Veterinary Services, has approved to receive mares over 731 days of age in accordance with the provisions of paragraph (a)(9) of this section.

(ii) The following States have been approved to receive mares over 731 days of age pursuant to § 92.2(i)(2)(v):

The State of California.
The State of Colorado.
The State of Kentucky.
The State of Louisiana.
The State of Maryland.
The State of New York.
The State of Ohio.
The State of South Carolina.
The State of Tennessee.
The State of Virginia.
The State of Wisconsin.

(9) In order for a State to be approved to receive mares over 731 days of age pursuant to § 92.2(i)(2)(v), the following conditions must be met:

(i) The State must enter into a written agreement with the Deputy Administrator, Veterinary Services, whereby the State agrees to enforce its laws and regulations to control contagious equine metritis (CEM) and to abide by the conditions of approval established by the regulations in this part; and

(ii) The State must agree to quarantine all mares over 731 days of age imported from countries listed in § 92.2(i)(1), pursuant to § 92.2(i)(2)(v), until such mares have been treated in accordance with the provisions of this paragraph; and

(iii) The State must have laws and regulations to insure that mares over 731 days of age imported from countries listed in § 92.2(i)(1), pursuant to § 92.2(i)(2)(v), have been treated and handled in the following manner:

(A) For 5 consecutive days, an accredited veterinarian shall aseptically clean and wash (scrub) the external genitalia and vaginal vestibule, including the clitoral fossa with a solution of not less than 2 percent chlorhexidine in a detergent base and then fill the clitoral fossa and coat the external genitalia and vaginal vestibule with an ointment of not less than 0.2 percent nitrofurozone.

(B) After an interim of 7 days following the 5th consecutive day of scrubbing the external genitalia and vaginal vestibule and filling the clitoral fossa:

(*1*) For any pregnant mare over 731 days of age, an accredited veterinarian shall collect 3 separate specimens from the clitoral fossa, at an interval of not less than 7 days between the collection of each set of specimens, and shall submit each specimen to a State or Federal animal disease diagnostic laboratory for culture. Seven days after foaling, an accredited veterinarian shall collect one specimen from the endometrium of the uterus of the mare and one specimen from the foal, and each specimen shall be submitted by the accredited veterinarian to a State or Federal animal disease diagnostic laboratory for culture. If the foal is female, this specimen shall be collected from the vaginal vestibule; and, if male, the specimen shall be collected from the prepuce.

(*2*) For any nonpregnant mare over 731 days of age, an accredited veterinarian shall collect three separate sets of specimens from the clitoral fossa, at an interval of not less than 7 days between the collection of each set of specimens, with one additional specimen collected from the endometrium of the uterus during estrus, and shall submit each specimen to a State or Federal animal disease diagnostic laboratory for culture.

(C) If any specimen required by this section or by § 92.2(i)(2)(v)(H) is found to be positive for CEM, the mare shall not be released from State quarantine except as provided in this paragraph. For such mare, an accredited veterinarian shall collect 3 additional separate sets of specimens from the clitoral fossa at not less than 7 days intervals between each set, with the first set collected not less than 1 year from the date of the last positive culture; and, 1 additional set of specimens shall be collected from the endometrium of the uterus during estrus. If the additional sets of specimens are negative for CEM, the mare may be released from quarantine.

(b) *Permit.* Except as provided in paragraph (e) of this section, when a permit is issued, the original and two copies will be sent to the importer. It shall be the responsibility of the importer to forward the original permit and one copy to the shipper in the country of origin, and it shall also be the responsibility of the importer to insure that the shipper presents the copy of the permit to the carrier and makes proper arrangements for the original permit to accompany the shipment to the specified U.S. port of entry for presentation to the collector of customs. Animals and animal semen and animal test specimens for diagnostic screening purposes for animals intended for importation into the United States for which a permit has been issued, will be received at the specified port of entry within the time prescribed in the permit which shall not exceed 14 days from the first day that the permit is effective for all permits, except that the time prescribed in permits for the importation of pet birds, commercial birds, zoological birds, poultry, or research birds, shall not exceed 30 days, and for performing or theatrical birds or poultry shall not exceed 90 days. Ruminants, swine, horses from countries listed in § 92.2(i)(1) of the regulations, poultry, poultry semen, animal semen, animal test specimens, and birds for which a permit is required by these regulations will not be eligible for entry if a permit has not been issued; if unaccompanied by such a permit; if shipment is from any port other than the one designated in the permit; if arrival in the United States is at any port other than the one designated in the permit; if the animals (including poultry and birds) or animal semen, or animal test specimens offered for entry differ from those described in the permit; if the animals or animal semen, or animal test specimens are not handled as outlined in the application for the permit and as specified in the permit issued; or in the case of ruminants and swine, if ruminants or swine other than those covered by import permits are aboard the transporting carrier.

(c) *Wild ruminants and wild swine from countries where foot-and-mouth disease or rinderpest exists.* (1) Wild ruminants and wild swine originating in the countries designated in Part 94 of this subchapter as countries in which foot-and-mouth disease or rinderpest exists may be carriers of such diseases even though the animals do not show clinical evidence of the diseases. In view of these circumstances and in order to prevent the introduction and dissemination of foot-and-mouth disease or rinderpest and protect the livestock of the United States, permits for the importation of wild ruminants, such as, but not limited to, giraffes, deer and antelopes, and of wild swine, will be issued only if such animals are intended for exhibition purposes in a zoological park previously approved by the Deputy Administrator, Veterinary Services in accordance with the standards specified in paragraph (c)(2) of this section and if the operator of such approved zoological park and the importer, if such operator and importer are different parties, have entered into the agreement set forth in paragraph (c)(3) of this section with Veterinary Services for the maintenance and handling of such wild ruminants and wild swine in the manner specified in the agreement to prevent the introduction and dissemination of communicable disease. For purposes of this paragraph "zoological park" means a zoo, park or other place maintained for the exhibition of live animals for recreational or educational purposes. The New York port of entry is the only port at which facilities are available which are adequate for the quarantining of wild ruminants and wild swine. Accordingly, permits issued for the importation of such wild animals will require that the animals be imported through the port of New York and quarantined at that port. The Deputy Administrator, Veterinary Services may cancel such a permit when he finds that any provision of this section or any other provision of the regulations has not been or is not being complied with.

(2) Approval of a zoological park for the receipt and maintenance of imported animals as described in this paragraph, shall be on the basis of an inspection, by an authorized representative of the Department, of the physical facilities of the establishment and its methods of operation. Standards for acceptable physical facilities shall include satisfactory pens, cages, or enclosures in which the animals can be maintained so as not to be in contact with the general public and free from contact with domestic livestock; natural or established drainage from the zoological park which will avoid contamination of land areas where domestic livestock are kept or with which domestic livestock may otherwise come in contact; provision for the disposition of manure, other wastes, and dead ruminants and swine within the zoological park; and other reasonable facilities considered necessary to prevent the dissemination of diseases from the zoological park. The operator of the zoological park shall have available the services of a full-time or part-time veterinarian, or a veterinarian on a retainer basis, who shall make periodic examinations of all animals maintained at the zoological park for evidence of disease; who shall make a post-mortem examination of each animal that dies; and who shall make a prompt report of suspected cases of contagious or communicable diseases to appropriate state or federal livestock sanitary officials.

(3) Prior to the issuance of an import permit under this section, the operator of the approved zoological park to which the animals are to be consigned, and the importer of the animals, if such operator and importer are different parties, shall execute an agreement covering each animal or group of animals for which the import permit is requested. The agreement shall be in the following form:

AGREEMENT FOR THE IMPORTATION, QUARANTINE AND EXHIBITION OF CERTAIN WILD RUMINANTS AND WILD SWINE

————, operator(s) of the zoological park known as ———— (Name) located at ———— (City and state), and ———— (Importer) hereby request a permit for the importation of ———— (Number and kinds of animals) for exhibition purposes at the said zoological park, said animals originating in a country where foot-and-mouth disease or rinderpest exists and being subject to restrictions under regulations contained in Part 92, Title 9, Code of Federal Regulations.

In making this request, it is understood and agreed that:

1. The animals for which an import permit is requested will be held in isolation at a port of embarkation in the country of origin, approved by the Deputy Administrator, Veterinary Services as a port having facilities which are adequate for maintaining wild animals in isolation from all other animals and having veterinary supervision by officials of the country of origin of the animals. Such animals will be held in such isolation for not less than 60 days under the supervision of the veterinary service of that country to determine whether the animals show any clinical evidence of foot-and-mouth disease, rinderpest, or other communicable disease and to assure that the animals will not have been exposed to such a disease within the 60 days next before their exportation from that country.

2. Shipment will be made direct from such port of embarkation to the port of New York as the port of entry in this country. If shipment is made by ocean vessel the animals will not be unloaded in any foreign port en route. If shipment is made by air, the animals will not be unloaded at any port or other place of landing except at a port approved by the Deputy Administrator, Veterinary Services as a port not located in a country where rinderpest or foot-and-mouth disease exists or as a port in such a country having facilities and inspection adequate for

maintaining wild animals in isolation from all other animals.

3. No ruminants or swine will be aboard the transporting vehicle, vessel or aircraft except those for which an import permit has been issued.

4. The animals will be quarantined for not less than 30 days in the Department's Animal Quarantine Station in Clifton, New Jersey.

5. Upon release from quarantine the animals will be delivered to the zoological park named in this agreement to become the property of the park and they will not be sold, exchanged or removed from the premises without the prior consent of Veterinary Services.

____
(Signature of importer)

Subscribed and sworn to before me this —— day of ———, 19—.

____
(Title or designation)

____
(Name of zoological park)

By ______________________________
(Signature of officer of zoological park)

____
(Title of officer)

Subscribed and sworn to before me this —— day of ———, 19—.

____
(Title or designation)

(d) *Animal semen from countries where rinderpest or foot-and-mouth disease exists.* Importation of semen of ruminants or swine, originating in any country designated in paragraph (a) of § 94.1 of this subchapter as a country where rinderpest or foot-and-mouth disease is determined to exist, is prohibited, except that semen from ruminants or swine originating in such a country may be offered for entry into the United States at the port of New York and later released from such port provided the following conditions have been fulfilled:

(1) The importer has applied for and obtained an import permit for the semen in accordance with the provisions of this section and related requirements concerning application therefor, which permit is in effect at the time of importation, and has deposited with the Department prior to the issuance of the permit sufficient funds so as to be available for defraying estimated expenses to be incurred in connection with the proposed semen importation and following the issuance of the permit has deposited such other amounts as may be required from time to time to defray unanticipated costs or increased expenses. Such an import permit may be denied for the reasons specified in paragraph (a)(3) of this section. Furthermore, an import permit will be revoked unless the following conditions have been complied with:

(i) The donor animal shall have been inspected on the farm of origin or on another premises (the inspection may be on another premises only if a veterinarian of the Department has traced the donor animal back to its farm of origin) by a veterinarian of the United States Department of Agriculture who, in cooperation with the veterinary service of the country of origin of the donor animal, shall have determined, insofar as possible, that the donor animal was never infected with rinderpest or foot-and-mouth disease; that the donor animal was never on a farm or other premise where rinderpest or foot-and-mouth disease then existed; that the donor animal had not been on a premises that had an animal that was susceptible to the virus of rinderpest or foot-and-mouth disease and that was exposed to either disease during the 12 months immediately prior to the date of inspection of the donor animal; that the donor animal, if a ruminant, has never been vaccinated against rinderpest; that the donor animal, if a swine, has never been vaccinated against rinderpest or foot-and-mouth disease; and that the donor animal was free from evidence of other communicable disease;

(ii) The donor animal shall have been permanently identified in a manner satisfactory to a veterinarian of this Department; a blood sample and an oesophageal-pharyngeal tissue sample (O-P sample) from such a donor ruminant and a blood sample from such a donor swine for tests as specified in paragraph (d)(1)(iv) of this section or other tests shall have been collected by a veterinarian of the United States Department of Agriculture and transported by air to the New York Port Veterinarian for delivery to the Foreign Animal Disease Diagnostic Laboratory, Greenport, New York, in containers approved by a veterinarian of this Department, sealed in the country of origin by a veterinarian of this Department; and pending the results of the tests, the donor animal shall have been kept in isolation on the farm of origin or other acceptable location under the supervision of a veterinarian of this Department, and during such isolation period no animal susceptible to rinderpest or foot-and-mouth disease shall have been permitted to enter such farm or location and no other source of exposure to rinderpest or foot-and-mouth disease shall have been present;

(iii) The blood samples from the donor animal shall have been negative to the tests specified in paragraph (d)(1)(iv) of this section made at the Foreign Animal Disease Diagnostic Laboratory, Greenport, New York, and to any other test for rinderpest, foot-and-mouth disease or other communicable disease prescribed by the Deputy Administrator, Veterinary Services.

(iv) In the case of a ruminant, each blood sample collected pursuant to paragraph (d)(1) (ii) or (vi) of this section shall have been tested for foot-and-mouth disease using the virus infection associated (VIA) test and each O-P sample collected pursuant to paragraph (d)(1) (ii) or (iv) of this section shall have been tested for foot-and-mouth disease using the virus isolation test. In the case of a swine, each blood sample collected pursuant to paragraph (d)(1) (ii) or (vi) of this section shall have been tested for foot-and-mouth disease using the virus infection associated (VIA) test and the virus neutralization test."[3]

(v) Following isolation, preliminary veterinary inspection, and testing while the donor animal was on the farm of origin or other acceptable location, the donor animal shall have been transported, under such conditions as the Department veterinarian prescribed to prevent exposure of the animal to the virus of rinderpest or foot-and-mouth disease, to an isolation facility properly equipped for the necessary care and maintenance of the donor animal and for the proper collection and handling of semen, approved by a veterinarian of this Department and under the direct supervision of such veterinarian;

(vi) The semen of the donor animal shall have been collected at the approved isolation facility under the direct supervision of a veterinarian of this Department (any number of collections may be made); such veterinarian shall take a 0.5 ml sample of semen from each semen collection; and all handling procedures, such as examination, dilution, refrigeration, and preparation of the semen for shipment, shall have been under the direct supervision of a veterinarian of this Department. In the case of a ruminant, a blood sample and an O-P sample shall have been taken from the donor animal by a veterinarian of the Department within 7 days after the final semen collection, and between 21 to 28 days after the taking of these samples another blood sample shall have been taken from the donor animal by a veterinarian of the Department. In the case of a swine, a blood sample shall have been taken from the donor animal by a veterinarian of the Department within 7 days after the final semen collection, and between 21 to 28 days after the taking of the sample, another blood sample shall have been taken from the donor animal by a veterinarian of the Department.

(2) The semen collected at the approved isolation facility shall have been at all times, except during air transportation to New York, in the custody of a veterinarian of this Department.

(3) The semen for which an import permit has been issued shall have been transported by air to the port of New York in liquid nitrogen containers approved by a veterinarian of this Department; sealed in the country of origin by a veterinarian of this Department; and accompanied by a statement by such veterinarian showing the identification of the donor animal and the dates the semen was collected,

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[3] The test procedures for the virus infection associated (VIA) test, the virus isolation test, and the virus neutralization test are available from the Chief, Foreign Animal Disease Diagnostic Laboratory, National Veterinary Services Laboratories, P.O. Box 848, Greenport, NY 11944.

along with a certificate regarding the health status of the donor animal as of the date of shipment of the semen to the port of New York. All semen received at the port of New York shall be held under quarantine in liquid nitrogen storage at such port in the custody of Veterinary Services until released or otherwise disposed of as provided in this section.

(4) The donor animal shall have been retained at the approved isolation facility in the country where the semen was collected until all of the applicable samples referred to in paragraph (d)(1)(vi) of this section have been collected by a veterinarian of the Department for tests as specified in paragraph (d)(1)(iv) of this section at the Foreign Animal Disease Diagnostic Laboratory, Greenport, New York, and any other tests as required by the Deputy Administrator, Veterinary Services.

(5) The semen sample from each collection shall have consisted of unprocessed semen without any added substances, and shall have been tested at the Foreign Animal Disease Diagnostic Laboratory, Greenport, New York. Such tests shall have been performed by injecting the semen samples into test animals which are susceptible to rinderpest or foot-and-mouth disease. The semen collected at the approved isolation facility, other than the semen samples, may be held in the country of origin or at the port of New York, at the option of the importer, until all of the testing required to be conducted under this section is completed.

(6) If it is determined that the requirements set forth in this paragraph have been complied with and there are no indications that the donor animal or the semen from the donor animal harbors the virus of rinderpest or foot-and-mouth disease or any other communicable disease and if the donor animal, blood samples from the donor animal, O-P samples (if applicable) from the donor animal, and semen samples from the donor animal are negative to all other tests required, the semen shall be released for shipment to the consignee listed by the importer; otherwise the semen shall be destroyed or disposed of as the Deputy Administrator, Veterinary Services may direct.

(Approved by the Office of Management and Budget under control numbers 0579-0040 and 0579-0060)

[28 FR 5971, June 13, 1963]

Editorial Note: For Federal Register citations affecting § 92.4, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 92.5 Certificate for ruminants, swine, poultry, pet birds, commercial birds, zoological birds, and research birds.

(a) *Ruminants and swine.* (1) All ruminants and swine offered for importation from any part of the world except as provided in §§ 92.20, 92.21, 92.22, 92.28, 92.35, 92.36, and 92.40 shall be accompanied by a certificate of a salaried veterinary officer of the national government of the country of origin stating that such animals have been kept in said country at least 60 days immediately preceding the date of movement therefrom and that said country during such period has been entirely free from foot-and-mouth disease, rinderpest, contagious pleuropneumonia, and surra: *Provided, however,* That certificates for wild ruminants or wild swine for exhibition purposes need specify freedom from the said diseases of the district of origin only: *And provided further,* That in the case of sheep, goats, and swine the certificate, as far as it relates to contagious pleuropneumonia, may specify freedom from such disease of the district of origin only. For domestic swine, the certificate shall also show that the entire country or origin is free of hog cholera, African swine fever, and swine vesicular disease and that for 60 days immediately preceding the time of movement from the premises of origin no swine erysipelas or swine plague has existed on such premises or on adjoining premises.

(2) The certificate accompanying sheep and goats offered for importation from any part of the world, except as provided in §§ 92.21, 92.28, and 92.36, shall, in addition to the statements required by paragraph (a)(1) of this section, state: (i) That the said salaried veterinary officer has inspected such sheep and goats on the

premises of origin and found them free of evidence of the disease known as scrapie, and of any other communicable disease; (ii) that, as far as it has been possible to determine, such animals have not been exposed to any such disease during the preceding 60 days; (iii) that, as far as can be determined, the disease known as scrapie has not existed in any district in which such sheep or goats were located during the three years immediately prior to shipment to the United States; and (iv) that each of such animals is not the progeny of a sire or dam that has been affected with scrapie.

(3) If ruminants or swine are unaccompanied by the certificate as required by paragraphs (a)(1) and (2) of this section, or if such animals are found upon inspection at the port of entry to be affected with a communicable disease or to have been exposed thereto, they shall be refused entry and shall be handled thereafter in accordance with the provisions of section 8 of the Act of August 30, 1890 (26 Stat. 416; 21 U.S.C. 103), or quarantined, or otherwise disposed of as the Deputy Administrator, Veterinary Services may direct.

(b) *Poultry.* (1) All poultry, except eggs for hatching, offered for importation from any country of the world shall be accompanied by a certificate of a salaried veterinary officer of the national government of the country of origin stating that such poultry and their flock or flocks of origin were inspected on the premises of origin immediately before the date of movement from such country and that they were then found to be free of evidence of communicable diseases of poultry, and that, as far as it has been possible to determine, they were not exposed to any such disease common to poultry during the 90 days immediately preceding the date of such movement and that these premises are not located in any area under quarantine during the preceding 90 days. Certificates for such poultry shall also state that the poultry have been kept in the country from which they are offered for importation for at least 90 days immediately preceding the date of movement therefrom or since hatched and that, as far as it has been possible to determine, no case of European fowl pest (fowl plague) or Newcastle disease occurred on the premises where such poultry were kept, or on adjoining premises, during that 90-day period. All eggs for hatching offered for importation from any part of the world, shall be accompanied by a certificate of a salaried veterinary officer of the national government of the country of origin stating that the flock or flocks of origin were found upon inspection to be free from evidence of communicable diseases of poultry, that no Newcastle disease has occurred on the premises of origin or on adjoining premises during the 90 days immediately preceding the date of movement of the eggs from such country, and that as far as it has been possible to determine such flock or flocks were not exposed to such disease during the preceding 90 days.

(c) *Birds.* All pet birds, except as provided for in paragraphs 92.2 (b) and (c), commercial birds, zoological birds and research birds offered for importation from any country of the world shall be accompanied by a certificate issued by a full-time salaried veterinary officer of the National Government of the country from which the birds are to be exported, stating that all birds covered by the certificate have been inspected by him and that no evidence of Newcastle disease, ornithosis, or other communicable disease of poultry was found among the birds and insofar as has been possible to determine, they were not exposed to any such disease during the 90 days immediately preceding their exportation; that such birds were placed into new containers at the premises from which the birds are to be exported; that such birds have not been vaccinated with Newcastle disease vaccine; that Newcastle disease did not occur anywhere on the premises from which the birds are to be exported or on adjoining premises during the 90 days immediately preceding the exportation of such birds and that these premises are not located in any area under quarantine for poultry diseases at any time during such preceding 90 days.

[28 FR 5971, June 13, 1963, as amended at 37 FR 5485, Mar. 16, 1972; 37 FR 9019, May 4, 1972; 37 FR 17465, Aug. 29, 1972; 37 FR 21149, Oct. 6, 1972; 38 FR 20610, Aug. 2, 1973; 38 FR 29883, Oct. 30, 1973; 40 FR 33650, Aug. 11, 1975; 44 FR 28300, May 15, 1979; 44 FR 42673, July 20, 1979]

§ 92.6 Diagnostic tests.

(a) *Tuberculosis and brucellosis tests of cattle.* Except as provided in §§ 92.20, 92.35 (b) and (c), and 92.43, all cattle offered for importation from any part of the world, except for immediate slaughter, shall be accompanied by a satisfactory certificate of a salaried veterinary officer of the national government of the country of origin showing that the animals have been tested for tuberculosis and brucellosis with negative results within 30 days of the date of their exportation: *Provided,* That the brucellosis test will not be required for steers, spayed heifers, or any cattle less than 6 months old. The said certificate shall give the dates and places of testing, names of the consignor and consignee, and a description of the cattle, with breed, ages, and markings.

(b) *Tuberculosis and brucellosis tests of goats.* Except as provided in §§ 92.21 and 92.36(b), all goats offered for importation, except for immediate slaughter, shall be accompanied by a satisfactory certificate of a salaried veterinary officer of the national government of the country of origin showing that the animals have been tested for tuberculosis and brucellosis with negative results within 30 days of the date of their exportation. The said certificate shall give the dates and places of testing, method of testing, names of consignor and consignee, and a description of the animals, including breed, ages, markings, and tattoo and eartag numbers.

(c) *Further tests during quarantine.* Animals that have been tested as prescribed in the paragraphs (a) and (b) of this section and that are subject to quarantine at the port of entry as provided in § 92.11, shall be retested during the last 10 days of the quarantine period under the supervision of a veterinary inspector, by one or more of the methods approved by the Deputy Administrator, Veterinary Services.

[28 FR 5971, June 13, 1963, as amended at 47 FR 49345, Nov. 1, 1982]

§ 92.7 Declaration and other documents for animals and animal semen.

(a) The certificates, declarations, and affidavits required by the regulations in this part shall be presented by the importer or his agent to the collector of customs at the port of entry, upon arrival of animals or animal semen at such port, for the use of the veterinary inspector at the port of entry.

(b) For all animals and animal semen offered for importation, the importer or his agent shall first present two copies of a declaration which shall list the port of entry, the name and address of the importer, the name and address of the broker, the origin of the animals or animal semen, the number, breed, species, and purpose of the importation, the name of the person to whom the animals or animal semen will be delivered, and the location of the place to which such delivery will be made.

(Approved by the Office of Management and Budget under control number 0579-0040)

[28 FR 5971, June 13, 1963, as amended at 48 FR 57472, Dec. 30, 1983]

§ 92.8 Inspection at the port of entry.

(a) Inspection shall be made at the port of entry of all horses, ruminants, swine, and poultry imported from any part of the world except as provided in §§ 92.25 and 92.33. All horses, ruminants, and swine found to be free from communicable disease and not to have been exposed thereto within 60 days prior to their exportation to the United States shall be admitted subject to the other provisions in this part; all poultry found to be free from communicable disease and not to have been exposed thereto within 90 days prior to their exportation to the United States shall be admitted subject to the other provisions in this part; all other animals and poultry except as provided in §§ 92.28(c) and 92.35(a) shall be refused entry. Animals refused entry, unless exported within a time fixed in each case by the Deputy Administrator of Veterinary

Services, and in accordance with other provisions he may require in each case for their handling shall be disposed of as the Deputy Administrator may direct in accordance with provisions of section 2 of the Act of July 2, 1962 (21 U.S.C. 134a), or the provisions of section 8 of the Act of August 30, 1890 (21 U.S.C. 103). Such portions of the transporting vessel, and of its cargo, which have been exposed to any such animals or their emanations shall be disinfected in such manner as may be considered necessary by the inspector in charge at the port of entry, to prevent the introduction or spread of livestock or poultry disease, before the cargo is allowed to land.

(b) All commercial birds, zoological birds and research birds imported from any part of the world shall be subjected to inspection at the Customs port of entry by a veterinary inspector of Veterinary Services and such birds shall be permitted entry only at the following ports of entry: Boston, Massachusetts; New York, New York; Miami, Florida; Tampa, Florida; New Orleans, Louisiana; Brownsville, Texas; El Paso, Texas; San Diego, California; San Ysidro, California; Los Angeles, California; San Francisco, California; Honolulu, Hawaii; Seattle, Washington; Chicago, Illinois, and Detroit, Michigan.

(c) All pet birds imported from any part of the world, except pet birds from Canada and pet birds meeting the provisions of § 92.2(c)(2), shall be subjected to inspection at the Customs port of entry by a veterinary inspector of Veterinary Services and such birds shall be permitted entry only at the ports listed in § 92.3(e). Pet birds of Canadian origin and those birds meeting the provisions of § 92.2(c)(2) shall be subject to veterinary inspection at any of the ports of entry listed in § 92.3.

[37 FR 9021, May 4, 1972, as amended at 38 FR 29883, Oct. 30, 1973; 40 FR 33650, Aug. 11, 1975; 40 FR 44306, Sept. 26, 1975; 44 FR 42673, July 20, 1979]

§ 92.9 Articles accompanying animals.

No litter or manure, fodder or other aliment, nor any equipment such as boxes, buckets, ropes, chains, blankets, or other things used for or about animals governed by the regulations in this part, shall be landed from any conveyance except under such restrictions as the inspector in charge at the port of entry shall direct.

§ 92.10 Movement from conveyances to quarantine station.

Platforms and chutes used for handling imported ruminants or swine shall be cleaned and disinfected under Veterinary Services supervision after being so used. The said animals shall not be unnecessarily moved over any highways nor allowed to come in contact with other animals, but shall be transferred from the conveyance to the quarantine grounds in boats, cars, or vehicles approved by the inspector in charge at the port of entry. Such cars, boats, or vehicles shall be cleaned and disinfected under Veterinary Services supervision immediately after such use, by the carrier moving the same. The railway cars so used shall be either cars reserved for this exclusive use or box cars not otherwise employed in the transportation of animals or their fresh products. When movement of the aforesaid animals upon or across a public highway is unavoidable, it shall be under such careful supervision and restrictions as the inspector in charge at the port of entry and the local authorities may direct.

§ 92.11 Quarantine requirements.

(a) *Cattle.* (1) Cattle imported from any part of the world except Canada, countries of Central America and the West Indies, and Mexico shall be quarantined for not less than 30 days, counting from the date of arrival at the port of entry.

(2) Cattle imported from Canada, countries of Central America and the West Indies, and Mexico shall be subject to the provisions of §§ 92.20, 92.28, 92.34, and 92.35, respectively.

(b) *Other ruminants and swine.* (1) Swine and ruminants other than cattle imported from any part of the world except Canada, shall be quarantined for not less than 15 days, counting from the date of arrival at the port of entry. During their quarantine, wild ruminants and wild swine shall be subject to such inspections, disinfection, blood tests, or other tests as may be required by the Deputy Administrator, Veterinary Services to determine their freedom from disease and the infection of disease.

(2) Sheep and goats imported from Canada shall be subject to the provisions of §§ 92.21 and 92.22, respectively. Ruminants imported from countries of Central America and the West Indies shall be subject to the provisions of § 92.28. Ruminants other than cattle imported from Mexico shall be subject to the provisions of §§ 92.34 and 92.36.

(c) *Poultry.* (1) All poultry imported from any part of the world, except as provided in § 92.26 shall be quarantined for not less than 30 days, counting from the date of arrival at the port of entry. During their quarantine, such poultry shall be subject to such inspections, disinfections, blood tests, or other tests as may be required by the Deputy Administrator, Veterinary Services, to determine their freedom from disease or the infection of disease, and their freedom from exposure thereto.

(d) *Horses.* (1) Except as provided in this section, horses intended for importation into the United States from any part of the world shall be shipped directly to a port designated in § 92.3 and be quarantined at said port until negative results to port of entry tests are obtained and the horses are certified by the port veterinarian to be free from clinical evidence of disease.

(i) Except as provided in §§ 92.24 and 92.34 with respect to horses from Canada and Mexico, horses intended for importation from the Western Hemisphere shall be quarantined at a port designated in § 92.3 for not less than 7 days.

(ii) Horses intended for importation from any country on the continent of Africa, or that have been in or transited any country on the continent of Africa shall enter the United States only at the Port of New York, New York, and be quarantined there for not less than 60 days.

(iii) In order to qualify for release from quarantine, all horses from any part of the world, while quarantined shall test negative to the following port of entry tests: an official test for dourine, glanders, equine piroplasmosis, and equine infectious anemia[6] and such other tests, inspections, disinfections and precautionary treatments that may be required by the Deputy Administrator, Veterinary Services, to determine their freedom from communicable diseases.

(iv) Any quarantine period required for a horse shall be counted using the first day after arrival of the horse at the quarantine facility as the first day of quarantine and may be extended for such additional period as the Deputy Administrator, Veterinary Services, may require to determine its freedom from disease. Any horse which is positive to any of the port of entry tests named in this paragraph or any other test required by the Deputy Administrator, Veterinary Services, or which is found by the port veterinarian to exhibit evidence of communicable disease during quarantine shall be refused entry into the United States and removed by the importer to a country other than the United States within 10 days of the date that the importer is notified by Veterinary Services that such horse has been refused entry into the United States. Upon request, the Deputy Administrator, Veterinary Services, may grant additional time for the removal of a horse from the United States in any case in which he determines that delay is unavoidable due to unforeseen circumstances and the additional time for removal of the horse will not present a threat of the spread of communicable disease to other animals in the United States. At the option of the importer, such horse may be disposed of in accordance with such conditions as the Deputy Administrator, Veterinary Services, believes necessary to prevent the dissemination of communicable disease into the United States. The importer shall be responsible for all costs of such removal or disposal.

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[6] In view of the fact that official tests for dourine and glanders are run exclusively at the Veterinary Services Laboratory, Beltsville, Maryland, protocols for these tests have not been published and are therefore not available; copies of "Protocol for the Complement-Fixation Test for Equine Piroplasmosis" and "Protocol for the Immuno-Diffusion (Coggins) Test for Equine Infectious Anemia" may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, Hyattsville, Maryland 20782, filed as part of the original document.

(2) *Special provisions.* Horses presented for entry into the United States as provided in § 92.3(g) of this part shall be quarantined in facilities provided by the importer and approved by the Deputy Administrator, Veterinary Services. Requests for approval and plans for proposed facilities shall be submitted no less than 15 days before the proposed date of entry of horses into the quarantine facility to the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, Hyattsville, MD 20782. Before the facility is approved, an inspection of the facility shall be made by a Veterinary Medical Officer of Veterinary Services, to determine whether it complies with the standards set forth in paragraph (d)(3) of this section: *Provided, however,* That approval of any quarantine facility and use of such facility shall be contingent upon a determination made by the Deputy Administrator that adequate personnel are available to provide services required by the facility. Approval of any facility may be refused and approval of any approved quarantine facility may be withdrawn at any time by the Deputy Administrator, Veterinary Services, upon his determination that any requirement of this section is not being met. Before such action is taken, the operator of the facility shall be informed of the reasons for the proposed action by the Deputy Administrator and afforded an opportunity to present his views thereon. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. The cost of the facility and all maintenance and operation costs of such facility shall be borne by the importer.

(3) *Standards and handling procedures for approval of quarantine facilities provided by the importer.* To qualify for designation as an approved quarantine facility provided by the importer for horses, the facility shall be maintained and operated in accordance with the following standards:

(i) *Supervision of the facility.* The facility shall be under the general supervision of a Veterinary Services veterinarian. Inspection and quarantine services shall be arranged by the importer of his agent with the Veterinarian in Charge, Veterinary Services, APHIS, USDA, for the State in which the approved facility is located [1], no less than 7 days before the proposed date of entry of the horses into the quarantine facility.

(ii) *Physical requirements for facility*—(A) *Location.* The facility shall be located and constructed to prevent horses from having physical contact with animals outside the facility.

(B) *Construction.* (*1*) The facility shall be constructed only with materials that can withstand repeated cleaning and disinfection in accordance with §§ 71.7 and 71.10 of Subchapter C of this Title. (All walls, floors and ceilings shall be constructed of solid impervious material or be screened as provided in paragraph (d)(3)(ii)(B)(*2*) of this section.)

(*2*) Doors, windows, and other openings of the facility shall be provided with double screens which will prevent insects from entering the facility.

(iii) *Sanitation and security.* (A) The importer shall arrange for a supply of water adequate to clean and disinfect the facility in accordance with §§ 71.7 and 71.10 of Subchapter C of this title.

(B) All feed and bedding used for horses in approved quarantine facilities shall originate from an area not under quarantine because of cattle fever ticks (see §§ 72.3 and 72.5 of Subchapter C of this title) and shall be stored within the facility.

(C) Upon the death or destruction of any horse, the importer shall arrange for the disposal of the animal carcass by incineration. Disposal of all other waste removed from the facility during the time horses are in quarantine or from horses which are refused entry into the United States shall be either by incineration or in a public sewer system which meets all applicable environmental quality control standards. Following completion of the quarantine period and the release of the horses into the United States all waste may be removed from the quarantine facility without further restriction.

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[1] The name and address of the Veterinarian in Charge of any State are available from the Deputy Administrator, Veterinary Services, APHIS, USDA, 6505 Belcrest Road, Hyattsville, Maryland 20782.

(D) The facility shall be maintained and operated in accordance with any additional requirements the Deputy Administrator, Veterinary Services, deems appropriate to prevent the dissemination of any communicable disease.

(E) The facility shall comply with all applicable local, State and Federal requirements for environmental quality.

(iv) *Operational procedures*—(A) *Personnel.* (*1*) Access to the facility shall be granted only to persons working at the facility or to persons specifically granted such access by the supervising Veterinary Services veterinarian. (*2*) The importer shall provide attendants for the care and feeding of horses while in the quarantine facility. (*3*) Persons working in the quarantine facility shall not come in contact with any horses outside the quarantine facility during the quarantine period for any horses in such quarantine facility.

(B) *Handling of horses in quarantine.* Horses offered for importation into the United States which are quarantined in an approved quarantine facility provided by the importer shall be handled in accordance with § 92.11(d)(1) while in quarantine.

(e) *Birds.* Each lot of pet birds, except as provided in § 92.2(c), commercial birds, zoological birds or research birds imported from any part of the world shall be quarantined for a minimum of 30 days, and for such longer period as may be required by the Deputy Administrator, Veterinary Services, in any specific case, on an "all-in, all-out" basis, at one of the ports of entry specified in § 92.8(b), at a USDA quarantine facility when arrangements have been made in advance by the importer and approval is granted in the permit described in § 92.4, or in facilities which have been approved by the Deputy Administrator as provided in paragraph (f) of this section. At a USDA quarantine facility each psittacine bird shall be individually identified by the Department within 72 hours of the entry of the bird into the bird quarantine facility with a serially numbered legband which has been coded to the quarantine facility or by other suitable means of identification. The identification device must be approved by the Deputy Administrator, Veterinary Services, before it shall be used to identify birds under this section. Such means of identification shall be supplied by the Department at cost to the importer. The Department shall make an identification record at the time such bird is so identified containing the species of the bird, including the common and scientific name, and the number of the identification device placed on the bird. Prior to use of an approved quarantine facility, a Cooperative and Trust Fund Agreement as set forth in paragraph (f)(7) of this section shall be executed by the operator of the facility and the Department and appropriate funds shall be deposited with the Deputy Administrator pursuant to the Cooperative and Trust Fund Agreement. During the quarantine period, the operator of the facility and the importer shall comply with handling procedures (including inspection and testing) as provided in paragraph (f) of this section. During the quarantine period, the importer shall comply with handling procedures, (including inspection and testing) as provided in paragraph (f) of this section. If the birds are found free of evidence of communicable diseases of poultry during quarantine, then the port veterinarian shall issue an agriculture release for entry through U.S. Customs. If the birds are found during port of entry inspection or during quarantine, to be infected with or exposed to a communicable disease of poultry, such birds shall be refused entry or shall be held for an additional period in quarantine until determined to be free of evidence of any communicable disease, or shall be otherwise disposed of as directed by the Deputy Administrator, Veterinary Services, in accordance with the provisions of section 2 of the Act of July 2, 1962 (21 U.S.C. 134a). See also paragraph (f)(3)(ii)(E) of this section.

(f) *Standards for approved quarantine facilities and handling procedures for importation of birds.* To qualify for designation as an approved quarantine facility[8] and to retain such approval, the facility and its maintenance and operation must meet the minimum requirements of paragraphs (f)(1) through (6) of this section: *Provided, however,* That approval of any quarantine facility shall be contingent upon a determination made by the Deputy Administrator that adequate personnel are available to provide services required by the facility if approved. The cost of the facility and all costs associated with the maintenance and operation of the facility shall be borne by the operator in accordance with the provisions of §§ 92.11(g) and 92.12 (a) and (c).

(1) *Supervision of the facility.* The facility shall be maintained under the supervision of the Veterinary Services port veterinarian at one of the ports listed in § 92.8(b).

(2) *Physical plant requirements.* The facility shall comply with the following requirements:

(i) *Location.* The quarantine facility shall be located:

(A) Within the immediate area of the port of entry to curtail to a minimum the possibility of introduction and dissemination of poultry diseases by the imported birds, while in transit from the point of entry to the quarantine facility;

(B) At least one-half mile from any concentration of avian species, such as, but not limited to, poultry processing plants, poultry or bird farms, pigeon lofts, or other approved quarantine facilities. Factors such as prevailing winds, possible exposure to poultry or birds moving in local traffic, etc., shall be taken into consideration. If the quarantine facility consists of multiple units for handling separate lots of birds, the individual units shall be located at least one-half mile from each other with separate personnel working as handlers in each unit.

(ii) *Construction.* The unit or units making up the quarantine facility shall each consist of a building or buildings which shall:

(A) Be constructed only with materials that can withstand continued cleaning and disinfection. (All solid walls, floors, and ceilings shall be constructed of impervious material; all screening shall be metal; all openings to the outside shall be double-screened.);

(B) Have a bird holding area of sufficient size to prevent overcrowding of the birds in quarantine. (All access into this holding area shall be from within the building and each entryway into such area shall be equipped with self-closing, double doors: *Provided,* That emergency exits to the outside may exist in the bird holding area if required by local fire ordinances. Such emergency exits shall be constructed so as to permit their opening from the inside of the facility only.);

(C) Have a ventilation capacity sufficient to control moisture and odor at levels that are not injurious to the health of the birds in quarantine;

(D) Have a vermin-proof feed storage area;

(E) Have office space for recordkeeping;

(F) Have a separate necropsy room which shall have refrigerated storage space for carcasses retained for laboratory examination and facilities adequate for specimen preparation and carcass disposal;

(G) Have a separate area for washing facility equipment;

(H) Have a shower at the entrance into the area comprised of the bird holding and necropsy rooms and a clothes storage and change area at each end of the shower area;

(I) Have a storage area for equipment necessary for quarantine operations;

(J) Have equipment necessary to maintain the facility in clean and sanitary condition, including insect and pest control equipment;

(K) Have a receptable for soiled and contaminated clothing in the clothes change area located nearest the entrance to the bird holding area.

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[8] Information as to the identity of such facilities may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

(iii) *Sanitation and security.* Arrangements shall exist for:

(A) A supply of water adequate to meet all watering and cleaning needs.

(B) Disposal of wastes by incineration or a public sewer system which meets all applicable environmental quality control standards;

(C) Control of surface drainage onto or from the facility to prevent any disease agent from entering or escaping;

(D) Protective clothing and footwear adequate to insure that workers at the facility have clean clothing and footwear at the start of each workday and at any time such articles become soiled or contaminated;

(E) Power cleaning and disinfecting equipment with adequate capacity to disinfect the facility and equipment;

(F) Sufficient stocks of a disinfectant authorized in § 71.10(a)(5) of this chapter;

(G) A security system which prevents contact of birds in quarantine with persons not authorized entry to the facility and with other birds and animals. Such a system shall include a daily log to record the entry and exit of all persons entering the facility and controls at all doorways and other openings to the facility to prevent escape or accidental entry of birds.

(3) *Operational procedures.* To retain designation as an approved quarantine facility, the following procedures shall be observed at the facility at all times.

(i) *Personnel.* Access to the facility shall be granted only to persons working at the facility or to persons specifically granted such access by the Veterinary Services port veterinarian.

(A) All personnel granted access to the bird holding area shall:

(*1*) Wear clean protective clothing and footwear upon entering the bird holding area;

(*2*) Change protective clothing and footwear when they become soiled or contaminated;

(*3*) Shower when entering or leaving the bird holding and necropsy areas.

(B) The operator of the facility shall handle soiled clothing worn within the quarantine unit in a manner approved by the Veterinary Services port veterinarian as adequate to preclude transmission of a poultry disease agent from the facility.

(ii) *Handling of the birds in quarantine.* The birds shall be kept in the quarantine facility for a minimum of 30 days and while in quarantine shall be handled in compliance with the following requirements:

(A) Each lot of birds to be quarantined shall be placed in the facility on an "all-in, all-out" basis. No birds shall be taken out of the lot while it is in quarantine except for diagnostic purposes and if additional birds are added to a lot, the total quarantine period for that lot shall be extended so that all birds will have completed at least 30 consecutive days of quarantine before release for entry into the commerce of the United States. The quarantine period may be extended as provided in paragraph (e) of this section;

(B) The birds shall not be vaccinated prior to release from the quarantine;

(C) Birds of the psittacine family shall receive a balanced, medicated feed ration treatment containing not less than 1% CTC with not more than 0.7% calcium for the entire quarantine period as a precautionary measure against chlamydiosis (psittacosis).

(D) The facility operator shall immediately collect all birds which die in quarantine and hold them under refrigeration, within the facility, shall account for all birds in the shipment, and shall not dispose of any carcass or parts thereof unless authorized to do so by a Veterinary Medical Officer of Veterinary Services of the Department. Birds that die enroute to the United States or while in quarantine shall be made available at the port of entry for necropsy by a Department poultry disease diagnostician who may submit specimens from such birds for laboratory examination.

(E) During the period of quarantine, the birds shall be subjected to such tests and procedures as are required in specific cases by the Veterinary Services port veterinarian, to determine whether the birds are free from communicable diseases of poultry and it shall be the responsibility of the facility operator to identify individually each psittacine bird within 72 hours of the entry of the bird into the quarantine facility with a serially numbered legband which has been coded to the quarantine facility or by other suitable means of identification. Any identification device must be approved by the Deputy Administrator, Veterinary Services, upon written request to him, before it shall be used to identify birds under this section. Such means of identification shall be supplied by the facility operator, and the facility operator shall insure that each bird is so identified at the time the bird is released from the facility. If frank or clinical Newcastle disease occurs among any birds in quarantine, all birds in the facility shall be destroyed or refused entry and the entire facility shall be thoroughly cleaned and then disinfected as directed under the supervision of a Veterinary Services inspector.

(F) The quarantine facility from which a lot of birds has been released shall be thoroughly cleaned and disinfected with a disinfectant authorized in § 71.10(a)(5) of this chapter, under supervision of a Veterinary Services inspector before a new lot is placed in the facility.

(iii) *Records.* It shall be the responsibility of the operator of the facility to maintain a current daily log for each lot of birds, recording such information as the general condition of the birds each day, source of origin of the birds in the lot, total number of birds in the lot when imported, number of dead birds when lot arrived, date lot was placed into the facility, number of deaths each day in the lot during the quarantine period, necropsy results, and laboratory findings on birds that died during the quarantine date of prescribed tests and results, Department import permit numbers of each lot, date lot was removed from the facility, and any other observations pertinent to the general health of the birds in the lot. The operator of the facility shall also make an identification record, at the time each psittacine bird is identified, containing the species of the bird, including the common and scientific name and the number of the identification device placed on each psittacine bird. The daily log and the identification record shall be maintained for 12 months following the date of release of the bird from quarantine and shall be made available to Veterinary Services personnel upon request.

(4) Additional requirements as to location, security, physical plant and facilities, sanitation, and other items may be imposed by the Deputy Administrator, Veterinary Services, in each specific case in order to assure that the quarantine of the birds in such facility will be adequate to enable determination of their health status, prevent spread of disease among birds in quarantine, and prevent escape of poultry disease agents from the facility.

(5) *Selection of applicants for consideration for approval of bird quarantine facilities.* (i) When it is determined by the Deputy Administrator, Veterinary Services, that adequate personnel are available to provide services for one or more bird quarantine facilities in addition to any bird quarantine facilities already being serviced, an announcement will be published in the FEDERAL REGISTER specifying the ports of entry at which openings exist and the number of openings at each port of entry. Applications for approval will be accepted only if received by the Import/Export Animals and Products Staff, VS, APHIS, USDA, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782, on or before 60 days after the announcement is published in the FEDERAL REGISTER. If there is more than one announced opening at a port of entry, an applicant may submit more than one application but may not submit more applications than the number of announced openings. An applicant shall submit a completed VS Form 17-11,[1] "Application for Approval of Quarantine Facilities for Birds," or shall submit a document which states that it is an application for approval of a quarantine facility for birds and which includes the following information (the same as that called for by VS Form 17-11):

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[1] VS Form 17-11 is available from the Import/Export Animals and Products Staff, VS, APHIS, USDA, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782.

(A) Applicant's name, address, and telephone number;

(B) Status of applicant, such as individual, partnership, or corporation (if incorporated, include State where incorporated and date of incorporation);

(C) Name, title, and address of intended operators, partners, officers, directors, holders or owners of 10 per centum or more of voting stock, and employees in a managerial or executive capacity;

(D) (Optional) Address where the bird quarantine facility will be located;

(E) (Optional) A drawing of the floor plan for the facility showing the location of bird holding areas, equipment storage areas, office areas, clothes storage and change areas, feed storage areas, necropsy room (showing entry and refrigeration), washing areas for equipment, shower areas, ventilation arrangements, and entries and exits;

(F) (Optional) Whether the water source of the facility will be public or private;

(G) (Optional) Whether disposal of waste from the facility will be by sewer or incinerator, or both;

(H) Whether priority status is requested, and, if so, the extenuating circumstances relied on for such request; and

(I) Date; certification by signature of the intended operator, partner, or officer; and title of such individual after the following language: "Application is hereby made for approval of a USDA Approved Quarantine Facility for bird importations. I certify that the information provided herein is true and correct to the best of my knowledge and belief, and agree to comply with the applicable regulations in 9 CFR Part 92."

(ii) If the number of applications for bird quarantine facilities at a specified port of entry does not exceed the number of announced openings, each application shall be considered for approval of a facility at that port of entry.

(iii) If the number of applications for bird quarantine facilities at a specified port of entry exceeds the number of announced openings, priority status for selection shall be given to applications from operators of currently approved facilities who request to transfer operations from a facility at a port of entry where they currently operate to a facility at a port of entry specified in the announcement if the Deputy Administrator, Veterinary Services, determines that there is a change in circumstances beyond the control of the operator which makes it impracticable to continue operations at the currently approved facility, such as termination of services from a Government agency or termination of services from airlines. The following procedures shall apply for selection for consideration applications eligible for priority status at a specified port of entry:

(A) If the number of applications eligible for priority status does not exceed the number of announced openings, each application eligible for priority status shall be considered for approval of a facility at that port of entry.

(B) If the number of applicants with one or more applications eligible for priority status at a specified port of entry is fewer than the number of openings but the number of applications eligible for priority status exceeds the number of openings, each applicant with one or more application eligible for priority status shall first be selected for consideration for approval of one facility at that port of entry. Then, if there is a sufficient number of remaining openings at that port of entry, each applicant who submitted two or more applications eligible for priority status shall be selected for consideration for approval of a second facility. However, if the number of applicants who submitted two or more applications eligible for priority status exceeds the number of remaining openings, the applicants to be selected for consideration for approval for a second opening shall be determined based on a drawing. The proceeding shall continue in this manner until there are no more openings.

(C) If the number of applicants with one or more applications eligible for priority status exceeds the number of announced openings, each of these applicants (regardless of the number of applications submitted) will be eligible to be selected for consideration for approval of no more than one new facility at that port of entry, and the selection of such applicants to be considered for approval shall be determined based on a drawing.

(iv) The following procedures shall apply for consideration of applications not included as eligible for priority status if one or more openings remain for bird quarantine facilities at a specified port of entry after all applications eligible for priority status have been selected for consideration (applicants selected for consideration for approval based on priority status are not eligible to be considered under these provisions for remaining openings in the same drawing in which they received priority status):

(A) If the number of applicants is fewer than the number of remaining openings but the number of applications exceeds the number of remaining openings, each applicant shall first be selected for consideration for approval of one facility at that port of entry. Then, if there is a sufficient number of remaining openings, each applicant who submitted two or more applications shall be selected for consideration for approval of a second facility. However, if the number of applicants who submitted two or more applications exceeds the number of remaining openings, the applicants to be selected for consideration for approval for a second opening shall be determined based on a drawing. The proceeding shall continue in this manner until there are no more openings.

(B) If the number of applicants exceeds the remaining number of announced openings, an applicant (regardless of the number of applications submitted by such applicant) will be eligible to be selected for consideration for approval of no more than one new facility at that port of entry, and the selection of such applicants to be considered for approval shall be determined based on a drawing.

(v) If a drawing is to be held, the participants in the drawing shall be notified by registered or certified mail of the date, place, and time of the drawing so that they may attend; however, attendance by participants is not required.

(vi) Applicants selected for consideration for approval of a bird quarantine facility shall be notified of such selection by registered or certified mail. As a condition of approval as a bird quarantine facility, the facility must comply with the requirements set forth in this section within 18 months from the date of notification. The Deputy Administrator, Veterinary Services, may refuse approval of any bird quarantine facility if an intended operator or a person responsibly connected with the business of the quarantine facility is or has been convicted of any crime set forth in paragraphs (f)(6)(ii)(B) or (f)(6)(ii)(C) of this section. Before a decision is made with respect to the eligibility of any facility for approval, a personal inspection of the facility shall be made by a Veterinary Medical Officer of Veterinary Services, to determine whether it complies with the standards set forth in this section. Approval of any bird quarantine facility shall be contingent on a determination made by the Deputy Administrator, Veterinary Services, that adequate personnel are available to provide services required by the facility if approved.

(6)(i) Approval of any facility may be refused and approval of any approved quarantine facility may be withdrawn at any time by the Deputy Administrator, Veterinary Services, for any of the reasons provided in paragraph (f)(6)(ii) of this section. Before such action is taken, the operator of the facility will be informed of the reasons for the proposed action and, upon request, shall be afforded an opportunity for a hearing with respect to the merits or validity of such action, in accordance with rules of practice which shall be adopted for the proceeding. However, such withdrawal shall become effective pending final determination in the proceeding, when the Deputy Administrator determines that such action is necessary to protect the public health, interest or safety. Such withdrawal shall be effective upon oral or written notification, whichever is earlier, to the operator of the facility. In the event of oral notification, written confirmation shall be given to the operator of the facility as promptly as circumstances permit.

This withdrawal shall continue in effect pending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Deputy Administrator.

(ii) Except as provided in paragraph (f)(6)(iv) of this section, the approval of a commercial bird quarantine facility may be denied or withdrawn if:

(A) Any requirement of this section is not complied with, or

(B) The operator or a person responsibly connected with the business of the quarantine facility is or has been convicted of any crime under any law regarding the importation or quarantine of any animal or bird, or

(C) The operator or a person responsibly connected with the business of the quarantine facility is or has been convicted of any crime involving fraud, bribery, or extortion or any other crime involving a lack of integrity needed for the conduct of operations affecting the importation of commercial birds, research birds or zoological birds.

(D) The approved quarantine facility has not been used to quarantine birds for a period of one year.

(iii) For the purposes of this section, a person shall be deemed to be responsibly connected with the business of the quarantine facility if such person has an ownership, mortgage, or lease interest in the facility's physical plant, or if such person is a partner, officer, director, holder or owner of 10 per centum or more of its voting stock, or an employee in a managerial or executive capacity.

(iv) The denial or withdrawal referenced in this paragraph (6) of this section, shall not be solely based upon the convictions of those persons responsibly connected with an approved commercial bird quarantine facility if, after issuance of a complaint and upon receipt of notification of such action from the Deputy Administrator, the operator of the approved quarantine facility enters into a consent agreement with the Deputy Administrator, Veterinary Services, in which it is agreed that the responsibly connected person identified in the notification shall not ever be associated with the approved quarantine facility and the operator complies with the provisions of the agreement. Violation of the consent agreement shall constitute independent grounds for withdrawal of approval of an approved quarantine facility.

(7) *Cooperative and Trust Fund Agreement for services required by operator of approved quarantine facilities for the importation of birds.* (i) When a quarantine facility for the importation of birds is approved by the Deputy Administrator as provided in paragraph (e) of this section, a Cooperative and Trust Fund Agreement as set forth in paragraph (f)(7)(iii) of this section shall be executed by the operator of the facility and the Department and, in conjunction therewith, the operator shall deposit with the Deputy Administrator, Veterinary Services, funds adequate to cover all costs incurred by the Department in providing services required for two complete quarantine periods in accordance with the provisions of the Cooperative and Trust Fund Agreement.

(ii) The Deputy Administrator is authorized to provide services required by the operator of an approved quarantine facility in conjunction with the importations made through the facility for the importation of birds when he determines that the operator has executed a Cooperative and Trust Fund Agreement specified in paragraph (f)(7)(iii) of this section and has deposited funds in connection therewith as provided in such agreement.

(iii) *Cooperative and Trust Fund Agreement.*

Cooperative and Trust Fund Agreement between——(name of operator) and the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services.

This Agreement is made and entered into by and between——(name of operator), hereinafter referred to as the Cooperator, and the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, hereinafter referred to as the Service, with respect to————(approved quarantine facility and address of facility). Whereas, the Service is authorized pursuant to section 2 of the Act of February 2, 1903, as amended, section 11 of the Act of May 29, 1884, as amended, and section 4 of the Act of July 2, 1962 (21 U.S.C. 111, 114a, and 134c, respectively), to regulate the introduction of animals into the United States in order to prevent the introduction of animal and poultry diseases into the United States; and

Whereas, the Cooperator represents parties interested in the importation of certain birds from countries presently under restrictions for such importation; and

Whereas, the Cooperator is equipped with quarantine facilities approved in accordance with Part 92, 9 CFR, for use in importing birds; and

Whereas, the Cooperator has requested the Service to conduct inspections, perform laboratory procedures, complete examinations, and supervise the isolation, quarantine, and care and handling of birds to insure that they meet the Department's quarantine requirements before release into the United States; and

Whereas, it is the intention of the parties hereto that such cooperation shall be for their mutual benefit and the benefit of the people of the United States;

Now therefore, for and in consideration of the promises and mutual covenants herein contained, the parties hereto do hereby mutually agree with each other as follows:

(A) *The Cooperator Agrees:*

(1) To operate the approved quarantine facility in accordance with all Federal Laws and regulations.

(2) To provide a current list of designated personnel employed by the Cooperator who will be used to handle and care for birds during a quarantine period. The list will include the legal names, current residential addresses, and social security numbers of the designated personnel. The list will be furnished to the port veterinarian at the time an application for an import permit to import birds into the quarantine facility is submitted to the Service. The list will be updated for any changes in or additions to the designated personnel in advance of such personnel working in the quarantine facility.

(3) To furnish to the Service a signed statement from each of the designated personnel employed by the Cooperator which provides that such personnel agree that for a period of 3 days from their most recent contact with birds in the approved quarantine facility, such personnel will refrain from having contact with other birds and poultry. Such condition shall not be applicable from the date that the birds are released from quarantine.

(4) To not permit any designated personnel which the Service determines to be unfit to be employed at a quarantine facility upon written notice from the Service. Such determination shall be based upon such employee's committing or aiding and abetting in the commission of any violation of Title 9, Code of Federal Regulations, Part 92. The Cooperator further agrees to suspend any designated employee from working at a quarantine facility when the Service has reason to believe that such employee has violated any provision of Title 9, Code of Federal Regulations, Part 92, and the Deputy Administrator has determined that the actions of such employee constitute a severe threat to introduce or disseminate a communicable disease of poultry into the United States. Such action shall be made upon receipt of notice from the Service requiring such action by the Cooperator.

(5) To allow the unannounced entry into the quarantine facility of Service personnel or other persons authorized by the Service for the purpose of inspecting birds in quarantine, the operations at the quarantine facility and to ascertain compliance with the Standards for approved quarantine facilities and handling procedures for importation of birds contained in Title 9, Code of Federal Regulations, § 92.11(f).

(6) To provide permanent restrooms in both the clean and the quarantine areas of the approved quarantine facility.

(7) To provide a T.V. monitoring system or a window or windows sufficient to provide a full view of the quarantine area excluding the clothes changing area.

(8) To install a communication system between the clean and quarantine areas of the approved quarantine facility. Such communication system shall not interfere with the maintenance of the biological security of the quarantine area.

(9) To secure all windows and any openings in the quarantine facility in a manner satisfactory to the Department which will insure the biological security of the quarantine facility and prevent the unauthorized removal of birds.

(10) To install tamperproof hasps and to install hinges on doors from which the pins cannot be removed.

(11) To install a hood with a viewing window over the necropsy table.

(12) To bag waste material in leakproof bags. Such material shall be handled in a manner that spoilage is kept to a minimum and control of pests is maintained. Such material shall be disposed of by incineration or by public sewer or other method authorized by the Deputy Administrator to prevent the spread of disease. The disposition of such material shall only be under the direction and supervision of the Service.

(13) To feed chlortetracycline to psittacine birds, upon their arrival in the facility as prescribed in § 92.11(f)(3)(ii)(C).

(14) To install an electronic security system which is coordinated through or with the local police so that monitoring of the quarantine facility is maintained whenever Service personnel are not at the facility or, in lieu of such electronic monitoring system to arrange for continuous guarding of the facility with personnel from a

bonded, security company. *Provided*, That, if exotic Newcastle disease is diagnosed in any of the birds in the quarantine facility, continuous guarding of the facility with personnel from a bonded security company shall be maintained by the Cooperator. The electronic security system if installed shall be of the "silent type" and shall be triggered to ring at the monitoring site and not at the facility. The electronic system shall be approved by Underwriter's Laboratories.

Written instructions shall be provided to the monitoring agency which shall require that upon activation of the alarm, the police and a representative of the Service designated by the Service shall be notified by the monitoring agency. Such instructions, as well as any changes in such instructions, shall be filed in writing with the Deputy Administrator, Veterinary Services. The Cooperator shall notify the Service whenever a break in security occurs or is suspected of occurring.

(15) To not have non-Service personnel in the quarantine area when birds are in the quarantine facility unless Service personnel are present.

(16) To have seals of the Service placed on all entrances and exits of the facility when determined necessary by the Service and to take all necessary steps to insure that such seals are only broken in the presence of Service personnel.

(17) To decide what the disposition of a lot of birds will be within 48 hours following official notification that such a lot is infected with or exposed to velogenic viscerotropic Newcastle disease. Final disposition of the infected or exposed lot is to be accomplished within 4 working days following official notification. Disposition of the birds will be under the supervision of the Service.

(18) To furnish a telephone number or numbers to the Service at which the Cooperator can be reached on a daily basis or furnish the same for an agent or representative that can act and make decisions on the Cooperator's behalf.

(19) To deposit with the Service upon execution of this agreement the amount of $—— (equal to the approximate cost to the Department for two 30-day quarantine periods) to be used by the Service to defray all expenses incurred by the Service in providing services required, and as funds from that amount are obligated, monthly bills for costs incurred based on official accounting records will be issued to restore the deposit to its original level.

(20) To provide for the maintenance and operation of the approved quarantine facility in accordance with standards for approved guarantine facilities and handling procedures for importation of birds as provided in Part 92 of 9 CFR.

(B) *The Service agrees:*

(1) To furnish the services of technical and/or professional personnel needed to conduct inspections, perform laboratory procedures, complete examinations, and supervise the isolation, quarantine, and care and handling of birds being imported to insure that they meet the Department's quarantine requirements before release into the United States.

(2) To provide the Cooperator on a quarterly basis, or within 30 days following receipt of a written request from the Cooperator, with an accounting of funds expended in providing services under paragraph (B)(1) of this agreement. Any unobligated balance upon termination or expiration of this agreement shall be returned to the Cooperator.

(3) To issue or validate permits on a timely basis depending upon the availability of personnel.

(4) To inform the Cooperator when a diagnosis of VVND has been made in any facility.

(5) To promptly inform the Embassy or Consulate of the foreign country to which lots of birds, refused entry into the United States due to a diagnosis of VVND, are to be shipped.

(6) To notify in writing the Cooperator of any designated employee which the Service believes should be suspended from work at the approved quarantine facility and the basis for such action. Similar notice shall be afforded to the designated employee. Subsequent to such suspension, the designated employee shall have the right to request an immediate review of such action by the Deputy Administrator, Veterinary Services, including presenting his views to the Deputy Administrator in an informal conference. If the Deputy Administrator makes a final determination that grounds existed to suspend such employee, he shall notify the Cooperator and the suspended employee of his decision and such employee shall be discharged by the Cooperator.

(7) Prior to any final determination being made by the Service concerning the discharge of any designated personnel employed by the Cooperator, the Service will inform, in writing, the Cooperator and the designated personnel of the basis for such action. If such person contests such action he or she shall be permitted to present his or her views to the Deputy Administrator, Veterinary Services, provided such request is made within 30 days of the receipt of the aforementioned written notice. If a final determination is made by the Deputy Administrator that such personnel should be discharged, he shall notify such personnel and the Cooperator of such determination.

(C) *It is mutually understood and agreed:*

(1) That a maximum capacity will be established for each approved quarantine lot.

This will be based upon the capacity of the approved quarantine facility to handle the birds. The number of birds on the permits will not exceed this capacity.

(2) If the seals referred to in paragraph (f)(7)(iii)(A)(16) of this section are broken by other than Service personnel, it will be considered a breach in security and an immediate accounting of all birds in the facility shall be made by the Service. If any birds are determined to be missing from the facility, the quarantine period will be extended for at least an additional 30-day period.

(3) During the performance of this cooperative work, the Cooperator agrees to be bound by the equal opportunity and nondiscrimination provisions as set forth in exhibit B and nonsegregation of facilities provisions as set forth in exhibit C, which are attached hereto and made a part hereof.

(4) No member of or delegate to Congress or resident commissioner, shall be admitted to any share or part of this agreement or to any benefit to arise therefrom; but this provision shall not be construed to extend to this agreement if made with a corporation of its general benefit.

(5) This agreement shall become effective upon date of final signature and shall continue indefinitely. This agreement may be amended by agreement of the parties in writing. It may be terminated by either party upon 30 days written notice to the other party.

Date ————————

Cooperator

Date ————————

Acting Administrator, Animal and Plant Health Inspection Service, U.S. Department of Agriculture

(g) *Charges for services.* The charges to be borne by the operator for services provided for quarantine facilities approved in accordance with paragraph (f) of this section shall be:

(1) The appropriate GS hourly rate (including appropriate premium pay in accordance with 5 U.S.C. 5541–5549) of the employee who actually performs the service, including his travel time and his travel expenses: *Provided, however,* Such time and travel expense shall not exceed the time and travel expense to and from his official duty station;

(2) Laboratory costs at $8.50 per sample, plus shipping charges per sample, and;

(3) A surcharge for overhead based on the most current historical data available showing the percentage of APHIS funds expended for administrative support.

Requirements of other Federal laws and regulations, such as the Department's Animal Welfare Regulations in Subchapter A of this chapter shall also apply as applicable to the quarantine facilities.

(Approved by the Office of Management and Budget under control numbers 0579–0040 and 0579–0060)

[28 FR 5971, June 13, 1963]

Editorial Note: For Federal Register citations affecting § 92.11, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 92.12 Feed and attendants for animals in quarantine.

(a) *Ports where quarantine facilities not maintained by Veterinary Services.* The importer, or his agent, of animals subject to quarantine under the regulations in this part shall arrange for acceptable transportation to the non-Governmental quarantine facility and for the care, feed, and handling of the animals from the time of unloading at the quarantine port to the time of release from quarantine. Such arrangements shall be agreed to in advance by the Deputy Administrator, Veterinary Services. All expenses resulting therefrom or incident thereto shall be the responsibility of the importer; Veterinary Services assumes no responsibility with respect thereto. The quarantine facility must be suitable for the quarantine of such animals and must be approved by the Deputy Administrator, Veterinary Services prior to the issuance of any import permit. The facilities occupied by animals should be kept clean and sanitary to the satisfaction of the inspector assigned to supervise the quarantine. If for any cause the care, feed, or handling of animals, or the sanitation of the facilities, is neglected, in the opinion of the inspector assigned to supervise the quarantine, such services may be furnished by Veterinary Services in the same manner as though arrangements had been made for such services as provided by paragraph (b) of this section, and/or the animals may be disposed of as the Deputy Administrator, Veterinary Services, may direct, including sale in accordance with the procedure described in paragraph (b) of this section. The importer, or his agent, shall request in writing such inspection and other services as may be required, and shall waive all claim against the United States and Veterinary Services or any employee of Veterinary Services for damages which may arise from such services. The Deputy Administrator, Veterinary Services, may prescribe reasonable rates for the services provided under this paragraph. When it is found necessary to extend the usual minimum quarantine period, the importer, or his agent, shall be so advised in writing and shall pay for such additional quarantine and other services required. Payment for all services received by the importer, or his agent, in connection with each separate lot of animals shall be made by certified check or U.S. money order prior to release of the animals. If such payment is not made, the animals may be sold in accordance with the procedure described in paragraph (b) of this section, or otherwise disposed of as directed by the Deputy Administrator, Veterinary Services.

(b) *Ports where quarantine facilities maintained by Veterinary Services.* The importer, or his agent, of animals subject to quarantine under the regulations in this part shall arrange for acceptable transportation to the quarantine facility, and for the care, feed, and handling of the animals from the time they arrive at the quarantine port to the time of release from quarantine. Such arrangements shall be agreed to in advance by the Deputy Administrator, Veterinary Services. The importer or his agent shall request in writing such inspection and other services as may be required, and shall waive all claim against the United States and Veterinarian Services or any employee of Veterinary Services, for damages which may arise from such services. All expenses resulting therefrom or incident thereto shall be the responsibility of the importer; Veterinary Services assumes no responsibility with respect thereto. The Deputy Administrator, Veterinary Services may prescribe reasonable rates for the services provided under this paragraph. When it is found necessary to extend the usual minimum quarantine period, the importer, or his agent, shall be so advised in writing and shall pay for such additional quarantine and other services required. Payment for services received by the importer, or his agent, in connection with each separate lot of animals shall be made by certified check or U.S. money order prior to release of the animals. If such payment is not made, the animals may be sold in accordance with the procedure described in this paragraph or otherwise disposed of as directed by the Deputy Administrator, Veterinary Services. When payment is not made and the animals are to be sold to recover payment for services received, the importer, or his agent, will be notified by the inspector that if said charges are not immediately paid or satisfactory arrangements made for payment, the animals will be sold at public sale to pay the expense of care, feed, and handling during that period. The sale will be held after the expiration of the quarantine period, at such time and place as may be designated by the General Services Administration or other designated selling agent. The proceeds of the sale, after deducting the charges for care, feed, and handling of the animals and other expenses, including the expense of the sale, shall be held in a Special Deposit Account in the United States Treasury for 6 months from the date of sale. If not claimed by the importer, or his agent, within 6 months from the date of sale, the amount so held shall be transferred from the Special Deposit Account to the General Fund Account in the United States Treasury.

(c) Amounts collected from the importer, or his agent, for service rendered shall be deposited so as to be available for defraying the expenses involved in this service.

[39 FR 23049, June 26, 1974]

§ 92.13 Quarantine stations, visiting restricted; sales prohibited.

Visitors shall not be admitted to the quarantine enclosure during any time that animals are in quarantine except that an importer (or his accredited agent or veterinarian) may be admitted to the yards and buildings containing his quarantined animals at such intervals as may be deemed necessary, and under such conditions and restrictions as may be imposed, by the inspector in charge of the quarantine station. On the last day of the quarantine period, owners, officers or registry societies, and others having official business or whose services may be necessary in the removal of the animals may be admitted upon written permission from the said inspector. No exhibition or sale shall be allowed within the quarantine grounds.

§ 92.14 Milk from quarantined animals.

Milk or cream from animals quarantined under the provisions of this part shall not be used by any person other than those in charge of such animals, nor be fed to any animals other than those within the same enclosure, without permission of the inspector in charge of the quarantine station and subject to such restrictions as he may consider necessary in each instance. No milk or cream shall be removed from the quarantine premises except in compliance with all State and local regulations.

§ 92.15 Manure from quarantined animals.

No manure shall be removed from the quarantine premises until the release of the animals producing same.

§ 92.16 Appearance of disease among animals in quarantine.

If any contagious disease appears among animals during the quarantine period special precautions shall be taken to prevent spread of the infection to other animals in the quarantine station or to those outside the grounds. The affected animals shall be disposed of as the Deputy Administrator, Veterinary Services may direct, depending upon the nature of the disease.

§ 92.17 Horses, certification, and accompanying equipment.

Horses offered for importation from any part of the world shall be accompanied by a certificate of a salaried veterinary officer of the national government of the country of origin showing that the animals described in the certificate have been in said country during the 60 days preceding exportation; that each animal has been inspected on the premises of origin and found free of evidence of communicable disease and, insofar as can be determined, exposure thereto during the 60 days preceding exportation; that each animal has not been vaccinated with a live or attenuated or inactivated vaccine during the 14 days preceding exportation; and insofar as can be determined, no case of African horse-sickness, dourine, glanders, surra, epizootic lymphangitis, ulcerative lymphangitis, equine piroplasmosis, Venezuelan equine encephalomyelitis, or equine infectious anemia has occurred on the premises of origin or on adjoining premises during the 60 days preceding exportation; and, except as provided in § 92.2(i)(2) (i), (ii), (iii), (iv), and (v), the horses have not been in any country listed in § 92.2(i)(1) as affected with CEM during the 12 months immediately prior to their importation into the United States; they have not been on any premises at any time during which time such premises were found by an official of the Veterinary Services of the national government of the country where such premises are located, to be affected with CEM; that the horses have not been bred by or bred to any horses from an affected premises; and that they have had no other contact with horses that have been found to be affected with CEM or with horses that were imported from countries affected with CEM: *Provided, however,* That in specific cases the Deputy Administrator, Veterinary Services may authorize horses, which have been vaccinated with an inactivated vaccine, to enter the United States when he determines that in such cases and under such conditions as he may prescribe such importation will not endanger the livestock in the United States, and such horses comply with all other applicable requirements of this part: *And provided, further,* That a horse presented for importation from a country where it has been for less than 60 days shall be accompanied by a like certificate similarly issued by a salaried veterinary officer of the national government of each country in which the horse has been during the 60 days immediately preceding shipment from the last country from which it is shipped to the United States. Dates during which the horse was in each country during the 60 days immediately preceding exportation to the United States shall be included as a part of the certification. Upon inspecting horses at the port of entry and before permitting them to leave the port of entry, the inspector may require their disinfection and the disinfection of their accompanying equipment as a precautionary measure against the introduction of foot-and-mouth disease or any other disease dangerous to the livestock of the United States.

[36 FR 13678, July 23, 1971, as amended at 42 FR 63385, Dec. 16, 1977; 43 FR 25418, June 13, 1978; 45 FR 1005, Jan. 4, 1980; 46 FR 50937, Oct. 16, 1981]

§ 92.18 Dogs for handling livestock.

Collie, Shepherd, and other dogs imported from any part of the world except Canada, Mexico, and countries of Central America and the West Indies which are to be used in the handling of sheep or other livestock, shall be inspected and quarantined at the port of entry for a sufficient time to determine their freedom from the tapeworm, Taenia coenurus. If found to be infested with such tapeworm they shall be properly treated under the supervision of a veterinary inspector at the port of entry until they are free from the infestation.

CANADA[9]

§ 92.19 Import permit and declaration for animals and animal semen.

(a) For ruminants, swine, poultry, and animal semen, intended for importation from Canada, the importer shall first apply for and obtain from Veterinary Services an import permit as provided in § 92.4: *Provided,* That an import permit is not required for poultry if offered for entry at a land border port designated in § 92.3(b): *And provided, further,* That an import permit is not required for ruminants or swine, or for semen from ruminants or swine, offered for entry at a land border port designated in § 92.3(b) if such animal or the donor animal, in the case of semen: (1) Was born in Canada or the United States, and has been in no country other than Canada or the United States, or (2) has been legally imported into Canada from some other country and unconditionally released in Canada so as to be eligible to move freely within that country without restriction of any kind and has been in Canada after such release for 60 days or longer.

(b) For all animals and animal semen offered for importation from Canada, the importer or his agent shall present two copies of a declaration as provided in § 92.7.

[31 FR 81, Jan. 5, 1966, as amended at 37 FR 5486, Mar. 16, 1972; 37 FR 17465, Aug. 29, 1972]

§ 92.20 Cattle from Canada.

(a) *Health certificates; detention at port of entry.* Cattle offered for importation from Canada shall be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government showing that said cattle have been inspected and found to be free from any evidence of communicable disease and that, as far as can be determined, they have not been exposed to any such disease during the preceding 60 days. Any such cattle may be detained at the port of entry and there subjected to such tests as may be required by the Deputy Administrator, Veterinary Services and the importer shall be responsible for the care, feeding, and handling of such cattle during the period of detention.

(b) *Tuberculin-test certificates.* Importations of cattle from Canada, for purposes other than immediate slaughter as provided in § 92.23, shall be in compliance with the following conditions and requirements:

(1) Cattle from Canadian-listed tuberculosis-free accredited herds shall

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[9] Importations from Canada shall be subject to §§ 92.19 to 92.26, inclusive, in addition to other sections in this part which are in terms applicable to such importations.

be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government showing them to be from such herds and that said herds have been tuberculin tested within 1 year of the date of importation. The date of such tuberculin test shall be shown on the certificate.

(2) Cattle from herds in accredited areas in Canada, other than accredited herds, shall be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government showing them to be from herds in such areas and that the animals offered for entry have been tuberculin tested with negative results within 30 days preceding their offer for entry. However, cattle from herds in such areas—other than range herds—in which one or more reactors to the tuberculin test have been disclosed shall not be imported until the said herds have reached full tuberculosis-free status under Canadian regulations.

(3) Cattle from herds in restricted areas in Canada—other than range cattle and cattle from accredited herds—shall be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government showing: (i) That they have been tuberculin tested with negative results within 30 days preceding their offer for entry, (ii) that all cattle in the herd or herds from which the animals proceed have been tuberculin tested with negative results not more than 12 months nor less than 90 days before the date of the offer for entry, and (iii) that the animals presented for entry, excepting only the natural increase in the herd, were included in the herd or herds of origin at the time of said herd tests. However, cattle from herds in such areas—other than range herds—in which one or more reactors to the tuberculin test have been disclosed shall not be imported until the said herds have reached full tuberculosis-free status under Canadian regulations.

(4) Range cattle[10] shall be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government showing them to be range cattle and that they have been tuberculin tested with negative results within 30 days preceding their offer for entry.

(5) No cattle other than range cattle or those from accredited herds shall be imported from areas in Canada that are neither restricted nor accredited under Canadian regulations, except for immediate slaughter as provided in § 92.23.

(c) *Brucellosis test or vaccination certificates.* Importations from Canada of cattle six months of age or older, except steers and all cattle for immediate slaughter, shall be in compliance with the following conditions and requirements:

(1) Cattle from herds designated as brucellosis certified free herds by the Canadian Government must comply with the provisions of this paragraph, paragraph (c)(2), paragraph (c)(3), or paragraph (c)(5) of this section to be imported into the United States. To comply with the provisions of this paragraph, such cattle must be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government. This certificate shall show them to be from such herds and that the cattle to be imported have been tested for brucellosis with negative results within 30 days prior to their date of entry. If one or more reactors or suspects are disclosed in such a herd as a result of a brucellosis test at any time, cattle from the herd shall not be imported into the United States unless after such test the cattle to be imported and the herd are tested for brucellosis and found negative and such cattle are accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government showing them to have been tested for brucellosis with negative results within 30 days preceding their offer for entry or the herd is officially certified by the Canadian Government as a brucellosis certified free herd under Canadian regulations.

(2) Cattle from brucellosis certified free provinces of Canada must comply with the provisions of this paragraph, paragraph (c)(1), paragraph (c)(3),

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[10] Cattle of the beef breeds raised under range conditions in the western provinces of Canada.

paragraph (c)(4), or paragraph (c)(5) of this section to be imported into the United States. To comply with the provisions of this paragraph, such cattle must be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government. The certificate shall show that the cattle originated from brucellosis certified free provinces of Canada, that the cattle imported have been tested for brucellosis with negative results within 30 days prior to their date of entry, and that the cattle originated from a herd that has been maintained as a herd unit for at least 1 year prior to their exportation. A herd unit is a herd in which all the cattle were born and raised within the herd or were moved directly from another herd located within the brucellosis certified free provinces of Canada, or were moved directly from a brucellosis certified free herd in accordance with Canadian requirements for movement into brucellosis certified free provinces of Canada. If any cattle in any herd show a positive reaction to a brucellosis agglutination test at any time, cattle from the herd shall not be imported into the United States unless, after such test, the cattle to be imported and the herd are negative to a brucellosis agglutination test and the cattle to be imported are accompanied by a certificate in accordance with this paragraph or the herd is designated by the Canadian Government as a brucellosis certified free herd. Cattle to be imported into the United States from brucellosis certified free provinces of Canada shall be (A)' moved entirely within the boundaries of the brucellosis certified free provinces of Canada from the farm of origin directly to the United States ports of entry of Eastport, Idaho; Houlton, Maine; Raymond, Opheim, and Sweetgrass, Montana; Pembina, Portal, and Dunseith, North Dakota; and Blaine, Sumas, Lyndon, and Oroville, Washington; or (B) such cattle shall be moved in a vehicle sealed with Canadian Government seals. If the cattle to be imported are shipped in sealed vehicles, the seal numbers shall be recorded on the certificate, and the seals may only be broken by a United States port veterinarian at the United States port of entry.

(3) All cattle imported from Canada must comply with the provisions of this paragraph, paragraph (c)(1), paragraph (c)(2), or paragraph (c)(5) of this section to be imported into the United States. To comply with the provision of this paragraph, cattle must be accompained by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government showing that the cattle originated from a herd which is officially certified by the Canadian Government as a brucellosis qualified for export herd. A brucellosis qualified for export herd is a herd which meets at least one of the following conditions:

(i) All of the cattle have been maintained as a herd unit for at least two years prior to importation and all of the cattle eligible for brucellosis testing (hereinafter referred to as eligible cattle) have been tested for brucellosis and found negative in accordance with Canadian requirements within 12 months of the date of importation: *Provided*, Such herd unit may include cattle which were born and raised within such herd unit during said period, or cattle which were moved directly from another herd unit of like status; *Provided, further*, Such herd unit may include any other cattle if: (*a*) Such other cattle have been tested for brucellosis and found negative within 30 days prior to entry into such herd unit and all eligible cattle in such herd unit have been tested for brucellosis and found negative not less than 90 days following the date when the last of such other cattle had been added to such herd unit or (*b*) all eligible cattle in the herd unit, including any additions of brucellosis-vaccinated female calves between the ages of 6 months and 18 months that originate from herds in which cattle have not been tested as described in paragraphs (c)(1) and (c)(3)(i) of this section, have been tested negative for brucellosis no less than 90 days nor more than 12 months prior to the date of importation.

(ii) All of the cattle are from herd units qualified under paragraph (c)(3)(i) of this section: *Provided*, That if all of the cattle are not from herd units qualified under paragraph (c)(3)(i) of this section, all eligible cattle, including brucellosis-vaccinated female calves between the ages of 6 and 18 months, have been tested for brucellosis and found negative to three laboratory tests administered at intervals of at least 90 days.

(4) All cattle from a brucellosis qualified for export herd offered for importation, except as described in paragraph (c)(5) of this section, shall be tested negative for brucellosis within 30 days prior to the date of importation into the United States.

(5) Female cattle under 18 months of age that are born in herds in which cattle were tested as described in paragraphs (c)(1), (c)(2), and (c)(3)(i) of this section are exempted from the test requirements for brucellosis: *Provided, however*, They are accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government showing that they were officially vaccinated against brucellosis as calves between the ages of 2-6 months (60-179 days old) for dairy breeds and from 2-10 months of age (60-299 days old) for beef breeds. The certificate accompanying such officially vaccinated cattle shall comply with paragraph (d) of this section except that it shall show, in lieu of the date and place of testing, the date of vaccination and the age of the animal at the time of vaccination.

(6) All cattle to be imported from Canada which originate from a brucellosis certified free herd, a brucellosis certified free province of Canada or a brucellosis—qualified for export herd shall move directly to the United States port of entry without contact with cattle which are not from a brucellosis certified free herd or a brucellosis certified free province of Canada or a brucellosis—qualified for export herd.

(d) *Certificates; information required.* The certificates prescribed in paragraphs (b) and (c) of this section shall give the dates and places of testing, names of the consignor and consignee, and descriptions of the cattle, including breed, ages, markings, and tattoo and eartag numbers.

[28 FR 5971, June 13, 1963, as amended at 42 FR 37535, July 22, 1977; 43 FR 28454, June 30, 1978; 45 FR 36358, May 30, 1980; 50 FR 30413, July 26, 1985]

§ 92.21 Sheep and goats from Canada.

(a) Sheep and goats offered for importation from Canada shall be accompanied by a certificate either issued by a salaried veterinarian of the Canadian Government or issued by a veterinarian authorized by the Canadian Government to issue such certificates and subsequently endorsed by a salaried veterinarian of the Canadian Government, thereby representing that the veterinarian issuing the certificate was authorized to do so. The certificate shall state: (1) That such animals have been inspected on the premises of origin and found free of evidence of scrapie, and of any other communicable disease; (2) that, as far as it has been possible to determine, such animals have not been exposed to any such disease during the preceding 60 days; (3) that, as far as can be determined, scrapie has not existed on any premises on which such sheep or goats were located during the 42 months immediately prior to shipment of the United States; (4) that each of such animals is not the progeny of a sire or dam that has been affected with scrapie; and (5) that, as far as it has been possible to determine, each of such animals is not a sheep or goat that would have been slaughtered under the current Canadian scrapie eradication program had that program been in effect since April 1957.

(b) If sheep or goats are unaccompanied by the certificate required by paragraph (a) of this section, or if they are found upon inspection at the port of entry to be affected with a communicable disease or to have been exposed thereto, they shall be refused entry and shall be handled thereafter in accordance with the provisions of section 8 of the act of August 30, 1890 (26 Stat. 416; 21 U.S.C. 103), or quarantined, or otherwise disposed of as the Deputy Administrator, Veterinary Services may direct.

(c) Sheep and goats for immediate slaughter may be imported from Canada without the certification prescribed in paragraph (a) of this section but shall be subject to the other applicable provisions of this part and shall be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government stating that: (1) The sheep and goats were inspected on the premises where assembled for shipment to the United States within the 30 days immediately prior to the date of export and were found free of evidence of communicable disease, and

(2) As far as can be determined, they have not been exposed to any such disease during the 60 days immediately preceding their exportation.

[28 FR 5971, June 13, 1963, as amended at 40 FR 7081, Feb. 19, 1975; 50 FR 27929, July 9, 1985]

§ 92.22 Swine from Canada.

(a) *For purposes other than immediate slaughter.* Swine offered for importation from Canada for purposes other than immediate slaughter shall be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government showing that said swine have been inspected on the premises of origin immediately before the date of movement therefrom and found to be free of evidence of communicable disease and that, as far as it has been possible to determine, they were not exposed to any such disease during the preceding 60 days; in addition, the certificate shall show that no hog cholera or swine plague has existed on the premises of origin or on adjoining premises for such 60 days.

(b) *For immediate slaughter.* Swine for immediate slaughter may be imported from Canada without certification as prescribed in paragraph (a) of this section but shall be subject to the provisions of §§ 92.8, 92.19, and 92.23.

§ 92.23 Animals from Canada for immediate slaughter.

Cattle, horses, sheep, goats, and swine imported from Canada for immediate slaughter shall be consigned from the port of entry directly to a recognized slaughtering establishment and there be slaughtered within two weeks from the date of entry.

[42 FR 20813, Apr. 22, 1977]

§ 92.24 Horses from Canada.

(a) Except as provided in paragraph (c) of this section, horses from Canada shall be inspected as provided in § 92.8(a); shall be accompanied by a certificate as required by § 92.17 which shall include evidence of a negative test for equine infectious anemia for which blood samples were drawn during the 180 days preceding exportation to the United States and which test was conducted in a laboratory approved by the Canada Department of Agriculture or the United States Department of Agriculture; *Except,* that animals accompanying their dams which were foaled after their dam was so tested negative need not be so tested; and shall otherwise be handled as provided in § 92.17: *Provided, however,* That certificates required for horses from Canada may be either issued or endorsed by a salaried veterinarian of the Canadian Government: *And provided, further,* That inspection is not required for horses imported from Canada under temporary Customs authorization for a stay not to exceed 72 hours, and arrangements may be made to provide inspection of horses imported from Canada for a stay in excess of 72 hours at a point in the United States, other than the Customs port of entry, when the Veterinary Services inspector having responsibility for imports through such port of entry determines that such action will not endanger the livestock of the United States.

(b) Horses of United States origin which enter Canada for periods of not more than 72 hours may re-enter the United States without veterinary inspection at the port of entry provided they are accompanied by the health certificate under which they were permitted entry into Canada and that they re-enter the United States via the same Customs port of entry through which they entered Canada.

(c) Horses for immediate slaughter may be imported from Canada without the certification prescribed in paragraph (a) of this section, but shall be subject to the other applicable provisions of this part, and shall be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government stating that: (1) The horses were inspected on the premises where assembled for shipment to the United States within the 30 days immediately prior to the date of export and were found free of evidence of communicable disease, and

(2) As far as can be determined, they have not been exposed to any such disease during the 60 days immediately preceding their exportation.

[38 FR 19813, July 23, 1973, as amended at 38 FR 22467, Aug. 21, 1973; 41 FR 18088, Apr. 30, 1976; 42 FR 20813, Apr. 22, 1977; 45 FR 8581, Feb. 8, 1980; 47 FR 38675, Sept. 2, 1982]

§ 92.25 Special provisions.

(a) *In-bond shipments from Canada.* (1) Cattle, sheep, goats, swine, horses, poultry and birds from Canada transported in-bond through the United States for immediate export shall be inspected at the border port of entry and, when accompanied by an import permit obtained under § 92.4 of this part and all conditions therein are observed, shall be allowed entry into the United States and shall be otherwise handled as provided in paragraph (d) of § 92.2. Animals not accompanied by a permit shall meet the requirements of this part in the same manner as animals destined for importation into the United States, except that the Deputy Administrator, Veterinary Services, may permit their inspection at some other point when he finds that such action will not increase the risk that communicable diseases of livestock and poultry will be disseminated to the livestock or poultry of the United States.

(2) *In-transit shipments through Canada.* Animals (including poultry) originating in the United States and transported directly through Canada may re-enter the United States without Canadian health or test certificates when accompanied by copies of the United States export health certificates properly issued and endorsed in accordance with regulations in Part 91 of this chapter: *Provided,* That, to qualify for entry, the date, time, port of entry, and signature of the Canadian Port Veterinarian that inspected the animals for entry into Canada shall be recorded on the United States health certificate, or a paper containing the information shall be attached to the certificate that accompanies the animals. In all cases it shall be determined by the veterinary inspector at the United States port of entry that the animals are the identical animals covered by said certificate.

(b) *Exhibition animals.* Except as provided for horses in § 92.24(b), animals, including poultry, from the United States which have been exhibited at the Royal Agricultural Winter Fair at Toronto or other publicly recognized expositions in Canada, including racing, horse shows, rodeo, circus, or stage exhibitions in Canada, and have not been in that country for more than 90 days are eligible for return to the United States without Canadian health or test certificates, if they are accompanied by copies of the United States health certificate, issued and endorsed in accordance with the export regulations contained in Part 91 of this chapter for entry into Canada: *Provided,* That in the case of horses for exhibition, including race horses, the certificates shall certify that negative results were obtained from official tests for equine infectious anemia for which blood samples were drawn within 180 days of the date that the horses are offered for return to the United States: *And, provided further,* That all the animals offered for re-entry upon exaimination by the veterinary inspector at the U.S. port of entry, are found by the inspector to be free of communicable diseases and exposure thereto and are determined to be the identical animals covered by said certificates or are the natural increase of such animals born after official test dates certified on the dam's health certificate, or that in the case of poultry, they otherwise qualified for entry into Canada under the Canadian regulations.

[43 FR 15138, Apr. 11, 1978, and 45 FR 8581, Feb. 8, 1980, as amended at 47 FR 38675, Sept. 2, 1982]

§ 92.26 Poultry from Canada.

Poultry imported from Canada is not required to meet the requirements of § 92.11(c) but shall meet all other requirements of this part applicable to poultry or to animals generally.

[38 FR 29885, Oct. 30, 1973]

COUNTRIES OF CENTRAL AMERICA AND WEST INDIES[11]

§ 92.27 Import permit and declaration for animals and animal semen.

(a) For ruminants, poultry, and animal semen intended for importation from countries of Central America or of the West Indies, the importer shall first apply for and obtain from Veterinary Services an import permit as provided in § 92.4: *Provided,* That the Deputy Administrator, Veterinary Services, when he finds that such action may be taken without endangering the livestock or poultry industry of the United States, may, upon request by any person, authorize the importation by such person, without such application or permit, from the British Virgin Islands into the Virgin Islands of the United States, of animals consigned for immediate slaughter, and such authorization may be limited to a particular shipment or extend to all shipments under this paragraph by such person during a specified period of time. The importation of cattle from any area infested with cattle fever ticks is prohibited except as provided in paragraph (c) of § 92.28.

(b) For all animals and animal semen offered for importation from countries of Central America or of the West Indies, the importer or his agent shall present two copies of a declaration as provided in § 92.7.

(c) All poultry offered for importation from countries of Central America and the West Indies shall also meet the additional requirements in §§ 92.5(b), 92.8, 92.11(c), and 92.12 to qualify for entry. All poultry which fail to meet these requirements shall be rejected entry and shall be disposed of as directed by the Deputy Administrator, Veterinary Services in accordance with applicable laws.

[28 FR 5971, June 13, 1963, as amended at 37 FR 5486, Mar. 16, 1972; 37 FR 17465, Aug. 29, 1972; 37 FR 21149, Oct. 6, 1972]

§ 92.28 Ruminants from Central America and the West Indies.

(a) Ruminants offered for importation from countries of Central America and the West Indies, except as provided in paragraph (c) of this section, shall be accompanied by a certificate of a salaried veterinarian of the national government of the country of origin stating that such animals have been in said country at least 60 days immediately preceding the date of shipment therefrom; that he has inspected such animals on the premises of origin and found them free from evidence of any communicable disease; and that, as far as it has been possible to determine, such animals have not been exposed to any such disease during the preceding 60 days. If no such veterinary officer is available in the country of origin, ruminants, other than sheep and goats, may be accompanied by an affidavit of the owner or importer stating that such animals have been in the country from which they were directly shipped to the United States for a period of at least 60 days immediately preceding the date of shipment therefrom, and that during such period no communicable disease has existed among them or among animals of their kind with which they have come in contact. Ruminants for which such affidavit is presented, unless imported for immediate slaughter, shall be quarantined at the port of entry at least seven days and during that time shall be subjected to such dipping, blood tests or other tests, as may be required by the Deputy Administrator, Veterinary Services to determine their freedom from communicable diseases. If imported for immediate slaughter, such animals shall be handled as provided in § 92.23.

(b) The certificate accompanying sheep and goats offered for importation from countries of Central America and the West Indies shall, in addition to the statements required by paragraph (a) of this section, state: (1) That the said veterinary officer has inspected such sheep and goats on the premises of origin and found them free of evidence of the disease known as scrapie; (2) that, as far as can be determined, scrapie has not existed in any district in which such sheep or goats were located during the three years immediately prior to shipment to the United States; and (3) that each of such animals is not the progeny of a sire or dam that has been affected with scrapie.

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[11] Importations from countries of Central America and the West Indies shall be subject to §§ 92.7 and 92.30 inclusive, in addition to other sections in this part which are in terms applicable to such importations.

(c) Cattle, which have been infested with or exposed to fever ticks, may be imported from the British Virgin Islands into the United States Virgin Islands, for immediate slaughter only, if they are free from fever ticks at the time of such importation; if they are entered through one of the ports designated in § 92.3 (d) and are consigned to a recognized slaughtering establishment with facilities approved by the Deputy Administrator, Veterinary Services for holding the animals in isolation until slaughtered, which shall be within 14 days after the date of entry into the United States Virgin Islands; and if they are accompanied by a certificate of a responsible official of the government of the British Virgin Islands certifying that the cattle originated in and are being shipped directly from the British Virgin Islands, that they are free of fever ticks, and that, as far as it has been possible to determine, such cattle are free from evidence of communicable disease and have not been exposed to any such disease common to animals of their kind, other than splenetic, southern, or tick fever, during the 60 days preceding their movement to the United States Virgin Islands.

(d) If ruminants are unaccompanied by the certificate or affidavit as required by paragraphs (a), (b), or (c) of this section, or if they are found upon inspection at the port of entry to be affected with a communicable disease or to have been exposed thereto, they shall be refused entry, except as provided in paragraph (c) of this section. Ruminants refused entry shall be handled thereafter in accordance with the provisions of section 8 of the act of August 30, 1890 (26 Stat. 416; 21 U.S.C. 103), or quarantined, or otherwise disposed of as the Deputy Administrator, Veterinary Services may direct.

[28 FR 5971, June 13, 1963; 36 FR 24928, Dec. 24, 1971, as amended at 39 FR 16853, May 10, 1974]

§ 92.30 Horses from Central America and the West Indies.

Horses from Central America and the West Indies shall be inspected as provided in § 92.8(a); shall be accompanied by a certificate and otherwise handled as provided in § 92.17; and shall be quarantined and tested as provided in § 92.11(d): *Provided*, That any such horses that are found to be infested with fever ticks, Boophilus annulatus, shall not be permitted entry until they have been freed therefrom by dipping in a permitted arsenical solution or by other treatment approved by the Deputy Administrator, Veterinary Services.

[36 FR 13679, July 23, 1971, as amended at 41 FR 18088, Apr. 30, 1976]

MEXICO [12]

§ 92.31 Import permits and applications for inspection for animals and animal semen.

(a) For ruminants, poultry, and animal semen intended for importation from Mexico, the importer shall first apply for and obtain from Veterinary Services an import permit as provided in § 92.4: *Provided*, That an import permit is not required for a ruminant offered for entry at a land border port designated in § 92.3(c), if such animal:

(1) Was born in Mexico or the United States, and has been in no country other than Mexico or the United States, and

(2) Has not, during the preceding 60 days been corralled, pastured, or held with, or bred by, or inseminated with semen from any ruminant which has been imported into Mexico from a country designated in § 94.1(a)(1) as infected with foot-and-mouth disease or rinderpest, and

(3) Is not pregnant as a result of having been bred by, or artifically in-

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[12] Importations from Mexico shall be subject to §§ 92.31 to 92.40, inclusive, in addition to other sections in this part which are in terms applicable for such importations.

seminated with semen from, a ruminant imported into Mexico from countries designated in § 94.1(a) as infected with foot-and-mouth disease or rinderpest.

(b) For ruminants, horses, and poultry intended for importation into the United States from Mexico, the importer or his agent shall deliver to the veterinary inspector at the port of entry an application, in writing, for inspection, so that the veterinary inspector and customs representatives may make mutually satisfactory arrangements for the orderly inspection of the animals. For all cattle, except those entering pursuant to the third proviso in § 92.35(d), and except for steers, an official record of negative brucellosis test conducted on the herd of origin as required in § 92.35(d) shall be presented to the veterinary inspector at the port of entry when application is made for inspection. The veterinary inspector at the port of entry will provide the importer or his agent with a written statement assigning a date when the animals may be presented for import inspection.

(Approved by the Office of Management and Budget under control number 0579-0040)

[34 FR 18450, Nov. 20, 1969, as amended at 37 FR 6459, Mar. 30, 1972; 37 FR 21149, Oct. 6, 1972; 37 FR 21804, Oct. 14, 1972; 45 FR 14018, Mar. 4, 1980; 48 FR 54215, Dec. 1, 1983; 48 FR 57472, Dec. 30, 1983]

§ 92.32 Declaration for animals and animal semen.

For all animals and animal semen offered for importation from Mexico, the importer or his agent shall present two copies of a declaration as provided in § 92.7.

§ 92.33 Inspection at port of entry.

(a) All horses, ruminants, and poultry offered for entry from Mexico, including such animals intended for movement through the United States in bond for immediate return to Mexico, shall be inspected at the port of entry, and all such animals found to be free from communicable disease and fever tick infestation, and not to have been exposed thereto, shall be admitted into the United States subject to the other applicable provisions of this part. Animals found to be affected with or to have been exposed to a communicable disease, or infested with fever ticks, shall be refused entry except as provided in § 92.35(b)(2). Ruminants refused entry shall be handled thereafter in accordance with provisions of section 8 of the Act of August 30, 1890 (26 Stat. 416; 21 U.S.C. 103) or quarantined or otherwise disposed of as the Deputy Administrator, Veterinary Services may direct. Horses and poultry refused entry, unless exported within a time fixed in each case by the Deputy Administrator, Veterinary Services, shall be disposed of as said Deputy Administrator may direct.

(b) Animals covered by paragraph (a) of this section shall be imported through ports, designated in § 92.3, which are equipped with facilities necessary for proper chute inspection, dipping, and testing, as provided in this part.

[28 FR 5971, June 13, 1963, as amended at 45 FR 14018, Mar. 4, 1980; 48 FR 54215, Dec. 1, 1983]

§ 92.34 Detention at port of entry and period of quarantine.

Horses intended for importation from Mexico shall be quarantined at a port designated in § 92.3 until they qualify for release from such quarantine. In order to qualify for such release, all horses while so detained shall test negative to an official test for dourine, glanders, equine piroplasmosis, equine infectious anemia,[7] and such other tests that may be required by the Deputy Administrator to determine their freedom from other communicable diseases. Such horses shall also be subjected to such other inspections and disinfections deemed necessary by the Deputy Administrator, and they shall be released from quarantine only if found to be free from any communicable disease upon inspection.

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[7] In view of the fact that official test for dourine and glanders are run exclusively at the National Veterinary Services Laboratory, Ames, Iowa, protocols for these tests have not been published and are therefore not available; copies of "Protocol for the Complement—Fixation Test for Equine Piroplasmosis" and "Protocol for the Immuno—Diffusion (Coggins) Test for Equine Infectious Anemia" may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, Hyattsville, Maryland 20782, filed as part of the original document.

[45 FR 26318, Apr. 18, 1980, and 45 FR 85438, Dec. 29, 1980]

§ 92.35 Cattle from Mexico.

(a) Cattle and other ruminants imported from Mexico, except animals being transported in bond for immediate return to Mexico or animals imported for immediate slaughter, may be detained at the port of entry, and there subjected to such disinfection, blood tests, other tests, and dipping as required in this part to determine their freedom from any communicable disease or infection of such disease. The importer shall be responsible for the care, feed, and handling of the animals during the period of detention.

(b) *Fever ticks.* (1) Except as provided in paragraph (b)(2) of this section all cattle offered for importation from Mexico, for purposes other than immediate slaughter, shall be accompanied by a certificate of a salaried veterinarian of the Mexican Government showing that he inspected the said cattle at the time of movement to the port of entry and found them free from any evidence of communicable disease and that, as far as it has been possible to determine, they have not been exposed to any such disease, including splenetic, southern, or tick fever, during the preceding 60 days and if shipped by rail or truck the certificate shall further specify that the cattle were loaded into clean and disinfected cars or trucks for transportation direct to the port of entry. They shall also be accompanied by a certificate of the importer, or his agent supervising the shipment, stating that while en route to the port of entry they have not been trailed or driven through any district or area infested with fever ticks. Notwithstanding such certificates, such cattle shall be detained as provided in paragraph (a) of this section and shall be dipped at least once, under the supervision of an inspector, in one of the permitted dips listed in § 72.13(b) of this chapter. The selection of the permitted dip to be used will be made by the port veterinarian in each case. The owner or his agent shall first execute an application for inspection and dipping as provided in paragraph (b)(2)(iii) of this section.

(2) Cattle which have been exposed to splenetic, southern or tick fever or which have been infested with or exposed to fever ticks, may be imported from Mexico into the State of Texas, except into areas quarantined because of said disease or tick infestation as specified in § 72.5 of Subchapter C of this chapter, provided the following conditions are strictly observed and complied with:

(i) The cattle shall be accompanied by a certificate of a salaried veterinarian of the Mexican Government showing that he has inspected the cattle and found them free from fever ticks and any evidence of communicable disease, and that, as far as it has been possible to determine, they have not been exposed to any such disease except splenetic, southern, or tick fever, during the 60 days immediately preceding their movement to the port of entry.

(ii) The cattle shall be shown by a certificate of a salaried veterinarian of the Mexican Government to have been dipped in a tickicidal dip within 7 to 12 days before being offered for entry.

(iii) The importer, or his duly authorized agent, shall first execute and deliver to an inspector at the port of entry an application for inspection and supervised dipping wherein he shall agree to waive all claims against the United States for any loss or damage to the cattle occasioned by or resulting from dipping, or resulting from the fact that they are later found to be still tick infested; and also for all subsequent loss or damage to any other cattle in the possession or control of such importer which may come into contact with the cattle so dipped.

(iv) The cattle when offered for entry shall receive a chute inspection by an inspector. If found free from ticks they shall be given one dipping in one of the permitted dips listed in § 72.13(b) of this chapter under the supervision of an inspector 7 to 14 days after the dipping required by paragraph (b)(2)(ii) of this section. The selection of the permitted dip to be used will be made by the port veterinarian in each case. If found to be infested with fever ticks, the entire lot of cattle shall be rejected and will not be again inspected for entry until 10 to 14 days after they have again been dipped in the manner provided by paragraph (b)(2)(ii) of this section.

(v) The conditions at the port of entry shall be such that the subsequent movement of the cattle can be made without exposure to fever ticks.

(c) *Tuberculosis.* (1) In addition to the provisions required in the certificate under paragraph (b) of this section, such certificate shall also show, with respect to all cattle from Mexico except cattle certified in accordance with § 92.40, that a review of the available herd history, including any tuberculin test results, traceback slaughter reports and post-mortem record, and any other available records or information do not indicate evidence of tuberculosis or exposure thereto during the preceding 60 days. The certificate shall also show, with respect to all cattle, except cattle certified in accordance with § 92.40 and steers, that the herd or herds from which the animals proceed have been tuberculin tested with negative results not more than 12 months nor less than 3 month before the date the animals are offered for entry into the United States and that the animals presented for entry, excepting only the natural increase in the herd, were included in the herd or herds of origin at the time of said herd test. The certificate shall further show, with respect to steers, except those certified in accordance with § 92.40, that each animal has been tested with negative results by a salaried veterinarian of the National Government of Mexico not more than 60 days before the date the animals are offered for entry into the United States: *Provided,* That for steers not so tested and certified, the importer may elect to have the tuberculin test completed at the port of entry under the supervision of the port veterinarian. The said certificate shall give the date and place of inspection, the date and place and results of the tuberculin test if applicable, the name of the herd owner, the name of the consignor and consignee, and an individual description of each animal including breed, age, sex, and tattoo or ear tag number. However, cattle, including steers, that originated in herds declared to be tuberculosis-accredited by the Government of Mexico in accordance with that country's standards do not have to comply with the other provisions of this subparagraph if they are moved directly to the U.S. port of entry from their herd of origin without having commingled with cattle from any herd not so accredited enroute to the port of entry, and they are accompanied by a health certificate, issued by a salaried veterinarian of the Government of Mexico, stating that the cattle originated in such a tuberculosis-accredited herd and identifying the animals by eartag or tattoo numbers.

(2) Cattle from a herd or herds in which one or more reactors to the tuberculin test have been disclosed shall not be eligible for importation until said herd or herds have reached full tuberculosis-free status under Mexican Government regulations.

(3) All bulls and female cattle accompanied by the certificate described herein shall be detained at the port of entry under the supervision of the port veterinarian until tested for tuberculosis with negative results: *Provided,* That if any reactor is disclosed in any lot when so tested at the port of entry, the entire lot shall be refused entry and the entire lot or any portion thereof shall not be eligible for importation until said lot has reached full tuberculosis-free status under Mexican Government regulations and the animals offered for entry have met the other applicable requirements of this section.

(d) *Brucellosis.* All cattle offered for importation into the United States from Mexico shall be individually identified with a numbered metal tag; and except in the case of steers, shall be eligible for entry into the United States only if, in addition to complying with other applicable provisions of this part, they:

(1) Are accompanied by a certificate of a salaried veterinarian of the Mexican Government stating:

(i) That such cattle originated in a herd in which all cattle (except calves under 6 months of age and steers) were tested for brucellosis not less than 30 days nor more than 90 days prior to the date of certification and were found to be negative;

(ii) The date and place such herd was tested; and

(iii) That the cattle in the herd have been isolated from all other cattle from the time the herd was tested negative for brucellosis to the date of the offer of the cattle for entry into the United States; and

(2) Except for calves under 6 months of age, are subjected to an additional test for brucellosis at the port of entry and are found negative to such test: *Provided*, That if any reactor is disclosed in any lot when so tested at the port of entry, the entire lot shall be refused entry and the entire lot or any portion thereof may not be reoffered for entry until retested and recertified in accordance with paragraphs (d) (1) and (2) of this section or any cattle found to be negative to such test and any calves under 6 months of age in such lot may enter if consigned and moved under U.S. Department of Agriculture seal and without diversion to a slaughtering establishment operating under the provisions of the Federal Meat Inspection Act or a slaughtering establishment specifically approved as specified in § 78.24 of this chapter for immediate slaughter, or if consigned and moved under U.S. Department of Agriculture seal and without diversion to a quarantined feedlot; as defined in § 78.1(oo) of this chapter and thereafter handled in accordance with the provisions of § 78.12(a) of this chapter: *Provided, further*, That if any suspect but no reactor is disclosed in any lot when so tested at the port of entry, any cattle found to be negative to such test and any calves under 6 months of age in such lot may enter without further restriction under this paragraph (d): *And provided further*, That any cattle other than cattle which are classified as a reactor or suspect to a test for brucellosis may enter the United States from Mexico without the certificate or any test otherwise required by this paragraph, if they are individually identified with a numbered metal tag and are consigned and moved to a slaughtering establishment for immediate slaughter, or to a quarantined feedlot, in accordance with the first proviso in this paragraph and otherwise comply with the applicable provisions of this part.

[28 FR 5971, June 13, 1963; 31 FR 81, Jan. 5, 1966, as amended at 34 FR 18450, Nov. 20, 1969; 38 FR 1578, Jan. 16, 1973; 38 FR 2961, Jan. 31, 1973; 38 FR 10724; May 1, 1973; 39 FR 999, Jan. 4, 1974; 45 FR 14018, Mar. 4, 1980; 48 FR 54215, Dec. 1, 1983]

§ 92.36 Sheep and goats and wild ruminants from Mexico.

(a) Sheep and goats offered for importation from Mexico shall be accompanied by a certificate of a salaried veterinarian of the Mexican Government stating: (1) That he has inspected such sheep and goats on the premises of origin and found them free of evidence of the disease known as scrapie, and of any other communicable disease; (2) that, as far as it has been possible to determine, such animals have not been exposed to any such disease during the preceding 60 days; (3) that, as far as can be determined, the disease known as scrapie has not existed in any district in which such sheep or goats were located during the three years immediately prior to shipment to the United States; and (4) that each of such animals is not the progeny of a sire or dam that has been affected with scrapie. If such sheep or goats are shipped by rail or truck the certificate shall further specify that such animals were loaded into cleaned and disinfected cars or trucks for transportation direct to the port of entry. Notwithstanding such certificate, such sheep and goats shall be detained or quarantined as provided in § 92.34 and shall be dipped at least once in a permitted scabies dip under supervision of an inspector.

(b) The certificate accompanying goats offered for importation from Mexico shall, in addition to the statements required by paragraph (a) of this section, state that such goats have been tested for tuberculosis and brucellosis with negative results within 30 days preceding their being offered for entry, and give the date and method of testing, the name of the consignor and of the consignee, and a description of the animals including breed, ages, markings, and tattoo and eartag numbers. Notwithstanding such certification, such goats shall be detained or quarantined as provided in § 92.34 and retested for brucellosis.

(c) If sheep or goats are unaccompanied by the certificate as required by paragraphs (a) and (b) of this section, or if they are found upon inspection or retesting, as provided for in this part, to be affected with a communicable disease or to have been exposed thereto, they shall be refused entry and shall be handled thereafter in accordance with the provisions of section 8 of the Act of August 30, 1890 (26 Stat. 416; 21 U.S.C. 103), or quarantined, or otherwise disposed of as the Deputy Administrator, Veterinary Services may direct.

(d) Certificates will not be required for wild ruminants, other than sheep and goats, originating in and shipped direct from Mexico, but such animals are subject to inspection at the port of entry as provided in § 92.33.

§§ 92.37—92.38 [Reserved]

§ 92.39 Horses from Mexico.

(a) Horses offered for entry from Mexico shall be inspected as provided in § 92.8(a) and § 92.33; shall be accompanied by a certificate and otherwise handled as provided in § 92.17; and shall be quarantined and tested as provided in § 92.34: *Provided*, That horses offered for importation from tick-infected areas of Mexico shall be chute inspected, unless in the judgment of the inspector a satisfactory inspection can be made otherwise. If upon inspection they are found to be apparently free from fever ticks, before entering the United States they shall be dipped once in a permitted arsenical solution or be otherwise treated in a manner approved by the Deputy.

[45 FR 14018, Mar. 4, 1980, as amended at 45 FR 26318, Apr. 18, 1980; 45 FR 85438, Dec. 29, 1980]

§ 92.40 Animals for immediate slaughter.

Ruminants, other than sheep and goats, and horses may be imported from Mexico, subject to the applicable provisions of §§ 92.31, 92.32, 92.33 and 92.35(b)(2) for immediate slaughter if accompanied by a certificate of a salaried veterinarian of the Mexican Government stating that he has inspected such animals on the premises of origin and found them free of evidence of communicable disease, and that, so far as it has been possible to determine, they have not been exposed to any such disease common to animals of their kind during the preceding 60 days, and if the animals are shipped by rail or truck, the certificate shall further specify that the animals were loaded into cleaned and disinfected cars or trucks for transportation directly to the port of entry. Such animals shall be consigned from the port of entry to a recognized slaughtering establishment and there slaughtered within 2 weeks from the date of entry. Such animals shall be moved from the port of entry in conveyances sealed with seals of the United States Government. Sheep and goats from any part of Mexico may be imported only in compliance with other applicable sections in this part.

[45 FR 14019, Mar. 4, 1980]

§ 92.41 Requirements for the importation of animals into the United States through the Harry S Truman Animal Import Center.

(a) *Procedures for special authorization issued on a lottery basis.* Because of the extended period of time required to process cattle intended for importation from countries affected with exotic diseases not otherwise eligible for importation into the United States, including foot-and-mouth disease, through the Harry S Truman Animal Import Center, (HSTAIC), special authorization shall be required before any animal may enter the facility for quarantine. Such authorization will be issued on a lottery basis in accordance with the following procedures:

(1) *Drawing; contents of applications and deposits.* For each importation of animals into the HSTAIC, a

drawing will be held of the names of applicants who desire to import animals into the facility at that particular time. Each applicant shall complete an application for importing animals through the HSTAIC which shall be received by Veterinary Services at least 5 days prior to the date of the drawing.[13] The applicant shall state on the application the number of animals he desires to import into the HSTAIC and their country of origin. Each application shall be accompanied by a certified check, money order, or letter of credit, consistent with the terms of this section and with the Cooperative and Trust Fund Agreement (9 CFR 92.41(c)), as determined by the Deputy Administrator, payable to the United States Department of Agriculture, Animal and Plant Health Inspection Service, in the amount of one thousand dollars ($1,000), for each animal for which special authorization is requested on the application: *Provided*, That if special authorization is granted, the $1,000 per head is nonrefundable: *Provided further*, That if a letter of credit is utilized, the effective date on such letter of credit must run to the date the animals are scheduled to be released from the HSTAIC or billings made by the Service have been paid. In the event the applicant does not receive special authorization for animals for which he has applied, the amount deposited with the application for each animal not so authorized will be returned. If the applicant receives special authorization, the deposited amount shall be applied against the total cost of importation of each animal. At least 30 days prior to any drawing, notice will be given in the FEDERAL REGISTER of the date, time and place of the drawing for interested persons to submit an application. The notice shall also designate the geographic areas from which animals will be considered for importation into the HSTAIC and shall also include the fee schedule for the proposed importation. All applicants, or their designated legal agents or representatives, shall be required to appear in person at the drawing. Such designated legal agent or representative shall have a notarized statement of authority signed by the applicant.

(2) *Drawing for special authorization*. At the time, date, and places specified in the Notice of Drawing, if there are more than 230 applicants, a Department employee shall consecutively draw the names of applicants, until a maximum of 230 names have been selected to receive special authorization to qualify one animal for entry into the United States through the HSTAIC. If there are less than 230 applicants for 230 animals or more, the procedure for the consecutive drawings for spaces shall be as follows: A drawing will be held of the names of those applicants seeking to import at least one animal into the HSTAIC. Then a drawing will be held on the names of applicants wishing to import at least two animals. If after these names have been selected, available space in the HSTAIC still exists, a drawing will be held of the names of those applicants seeking to import at least three animals into the center. This selection process shall continue in the same manner until no available space exists for importing animals into the HSTAIC. However, if the total applications received are for less than 230 animals, each applicant shall receive special authorization for the number requested on their application in accordance with the provisions of paragraph (a)(4) of this section. Further, if available space at the HSTAIC still exists at the designated time of the drawing, each of the applicants shall be offered an opportunity to request additional space(s). If the requests for additional space(s) exceed the space(s) available, a lottery drawing shall be conducted for the additional spaces in the same manner as provided above from those interested applicants. Each applicant shall receive special authorization for the additional space(s) in accordance with the provisions of paragraph (a)(4) of this section. At the end of the drawing when the total number of animals has

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[13] Application forms may be obtained upon request from and completed applications should be sent to Import-Export Animals and Products Staff, Veterinary Services, APHIS, U.S. Department of Agriculture, 6505 Belcrest Road, Room 815, Hyattsville, MD 20782.

been determined, the fee will be established in accordance with the graduated fee scale. If any person selected to receive a special authorization declines acceptance, the other applicants will be offered the opportunity to receive the special authorization as provided above in this paragraph. If any such additional authorization is not requested, the fee per animal shall increase in accordance with the graduated fee schedule: *Provided*, That if the total number of animals for which special authorizations are requested is not at least 50, there shall not be a lottery or importation pursuant to this paragraph, the deposits of applicants requesting special authorization pursuant to this paragraph shall be refunded and special authorization may be issued in accordance with the procedures set forth in paragraph (b) of this section.

(3) *Area of origin; limitations.* All applications received will be carefully reviewed prior to the public drawing. In the event applications are received for the importation of cattle which originate from areas in which conditions are considered to be unacceptable as specified in § 92.4(a)(3), the applicant will be so advised in writing and the money submitted with the application will be returned.

(4) *Requirements for special authorization.* On the day of the drawing applicants selected to receive special authorization for cattle to be qualified for importation through the HSTAIC, or their designated legal agents or representatives shall be required to execute a cooperative agreement described in paragraph (d) of this section and pay the required fee in accordance with the provisions of the cooperative agreement. Authorization to qualify cattle into the United States through HSTAIC shall not be assigned or transferred, not shall any interest be assigned or transferred.

(5) *Procedures for special authorization subsequent to the time of the initial drawing.* If the total number of cattle for which special authorization was requested at the time of the initial drawing was at least 50 and if available space at the HSTAIC still exists subsequent to the designated time of the initial drawing, the Deputy Administrator, Veterinary Services, may upon written request by an applicant or the applicant's designated legal agent or representative, provide an additional drawing and give special authorization for additional cattle to applicants granted special authorization at the initial proceeding, if the Deputy Administrator, Veterinary Services, determines that there is sufficient time for applicants and Veterinary Services personnel to make the necessary preparations for the importation of any additional cattle. Such special authorization for any additional cattle will be made in accordance with the procedures set forth in paragraphs (a) (1) through (4) of this section, except that the notice of the additional drawing shall be given to each applicant by registered or certified mail rather than by publication in the FEDERAL REGISTER, the notice of the additional drawing shall be required to be given to applicants only 10 days prior to the additional drawing rather than 30 days, calculations for the additional drawing shall be made based on the number of available spaces rather than on the number 230, applicants or their designated legal agents or representatives shall not be required to appear in person at the additional drawing unless they desire to make application for additional special authorizations at the time of the additional drawing, and applicants shall have 14 days after the drawing to submit an executed cooperative agreement described in paragraph (d) of this section and pay the required fee in accordance with the provisions of the cooperative agreement.

(b) *Procedures for special authorization for exclusive use of the HSTAIC.* Special authorization for exclusive use of the HSTAIC for between 50 and 230 animals shall be issued in accordance with the following procedures when it is not scheduled for use for an importation of animals pursuant to § 92.41(a).

(1) *The application.* Each applicant for special authorization for exclusive use of the HSTAIC shall complete an application for importing animals through the HSTAIC. The applicant shall also indicate on the application that the applicant is requesting special

authorization for exclusive use of the HSTAIC. The completed application shall then be sent to the Import-Export Animals and Products. Each application shall be valid only for the fiscal year (October 1-September 30) in which it is received by the Import-Export Animals and Products Staff.

(2) *Selection for special authorization for exclusive use of the HSTAIC.* Special authorization for exclusive use of the HSTAIC for between 50 and 230 animals shall be offered by the Department to the applicant whose valid completed application was first received by the Import-Export Animals and Products Staff. If the applicant declines this offer, or becomes ineligible, special authorization for exclusive use of the HSTAIC for between 50 and 230 animals shall be offered by the Department to the applicant whose valid completed application was the second one received by the Import-Export Animals and Products Staff. The Department shall continue this procedure as long as there are applications to be considered or until an applicant accepts the offer of special authorization. *Provided that,* during a fiscal year (October 1-September 30) no applicant shall be offered special authorization more than one time, unless there are no other applications from other applicants for special authorization for exclusive use of HSTAIC for the Department to consider.

(3) *Requirements for special authorization.*

(i) The applicant who accepts the offer of special authorization for exclusive use of the HSTAIC shall be sent a cooperative agreement, as provided in § 92.41(d), by certified mail, return receipt requested. The applicant shall execute and return to the Import-Export Animals and Product Staff the cooperative agreement within 14 calendar days of the applicant's receipt of the cooperative agreement and pay the required fee, or deposit the required payment bond or letter of credit, in accordance with the provisions of the cooperative agreement. Failure to return a completed cooperative agreement to the Import-Export Animals and Products Staff and pay the required fee, or deposit the required payment bond or letter of credit, within 14 calendar days of receipt of the cooperative agreement shall constitute a declination of the offer of special authorization. Authorization to qualify animals into the United States through the HSTAIC shall not be assigned or transferred, nor shall any interest therein be assigned or transferred.

(ii) In the event that any application is received for the importation of animals which originate in areas in which conditions are considered to be unacceptable as specified in § 92.4(a)(3), the applicant will be so notified in writing.

(c) *Fees.* (1) Cost associated with the maintenance and operation of the facility shall be borne by applicants who receive a special authorization under this section in accordance with the provisions of a cooperative agreement specified in paragraph (d) of this section.

(2) The Deputy Administrator is authorized to establish reasonable fees of the costs incurred by the Department in the maintenance and operation of the HSTAIC. Such fees shall include certain pre-entry services provided by the Department to prepare HSTAIC and animals for entry into that facility. Fees shall also include costs incurred while animals are in the facility and for a period of 30 days subsequent to the animals leaving the facility for costs incurred in its cleaning and disinfecting.

(3) The fees authorized in this section shall be based upon the following items:

(i) *Personnel.* The hourly rates including appropriate premium pay in accordance with 5 U.S.C. 5541-5549 for Veterinary Services' employees who perform the service.

(ii) *Travel.* The costs of travel and per diem of Veterinary Services' employees from their official duty station to their temporary duty station and return in order to qualify animals for entry into the facility. Travel costs shall also include costs to courier test samples from temporary duty stations overseas to Plum Island for testing.

(iii) *Utilities.* The cost of electricity, oil and water for operating the HSTAIC for the three month period of quarantine plus one month for cleaning and disinfection.

(iv) *Laboratory costs.* The cost of conducting three series of laboratory tests for each animal as authorized by the cooperative agreement and in accordance with a Veterinary Services protocol[12a] to qualify for importation into the Harry S Truman Animal Import Center.

(v) *Supplies.* The cost of supplies (feed, bedding, disinfectants, contact test animals and miscellaneous supplies for the animal care, maintenance, and testing at the facility) for the three month period of quarantine plus one month for cleaning and disinfection.

(vi) *Overhead.* A surcharge for overhead based on the most current historical data available showing the percentage of Animal and Plant Health Inspection Service funds expended for administrative support.

(4) Any test performed on animals in excess of the number of animals specified in a cooperative agreement is not included in the fees authorized in this section. The Deputy Administrator shall charge the importer for whom the service is performed the actual cost of conducting such test. Payment shall be due upon receipt by such person of a bill for the services from the Department.

(5) The cost of any additional laboratory tests deemed necessary by the Deputy Administrator to determine an animal's freedom from communicable disease is not included in the fees authorized in this section. Also, any treatment performed on animals while at the Harry S Truman Animal Import Center is not included in the fees authorized in this section. The Deputy Administrator shall charge the importer for whom the service is performed the actual cost of such testing or treatment. Payment shall be due upon receipt by that person of a bill for the services from the Department.

(6) The importer shall be reimbursed for any monies advanced for feed, bedding or laboratory tests for animals at the HSTAIC if such feed or bedding are not used or if such laboratory test for animals are not performed by Veterinary Services.

(7) Fees in Part I of the Agreement shall be based on the number of special authorizations to import animals through the HSTAIC that have been granted to all importers. Fees in Part II of the Agreement shall be based on the number of animals, for which special authorizations were granted to all importers, which have been qualified to enter the USDA-approved embarkation facility.

(d) *Cooperative agreements.* Each applicant, or their legal agent or representative, selected to be specially authorized to qualify animals for importation through the HSTAIC shall enter into and abide by the provisions of the following cooperative agreement with the Department. Financial obligation for the amount detailed in the following cooperative agreement is to be provided at the time the cooperative agreement is signed.

COOPERATIVE AND TRUST FUND AGREEMENT BETWEEN (NAME OF IMPORTER) AND THE UNITED STATES DEPARTMENT OF AGRICULTURE, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, VETERINARY SERVICES

This Agreement is made and entered into by and between (Name and address of importer) hereinafter referred to as the Cooperator, and the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, hereinafter referred to as the Service.

Whereas, the Service is authorized pursuant to section 2 of the Act of February 2, 1903, as amended, and section 1 of the Act of May 6, 1970 (21 U.S.C. 111 and 135, respectively) to regulate the introduction of animals into the United States in order to prevent the introduction of animal and poultry diseases into the United States; and

Whereas, the Cooperator is interested in the importation of animals into the United States through the Harry S Truman Animal Import Center (HSTAIC), established by the Service pursuant to 21 U.S.C. 135, for a quarantine period scheduled to begin on or about ——; and

Whereas, the Cooperator has requested the Service to conduct inspections, perform laboratory procedures, complete examinations, and supervise the isolation, quarantine, and care and handling of animals to insure that they meet the Department's requirements to enter a USDA-approved embarkation facility in the country of origin; and

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[12a] A protocol concerning the requirements to be observed may be obtained upon request from Import-Export Animals and Products Staff, Veterinary Services, APHIS, VS, U.S. Department of Agriculture, 6505 Belcrest Road, Room 819, Hyattsville, MD 20782.

Whereas, the Cooperator has requested the Service to conduct inspections, perform laboratory procedures, complete examinations, and supervise the isolation, quarantine, care and handling of animals to insure that they meet the Department's quarantine requirements at the USDA-approved embarkation facility in the country of origin and at the HSTAIC before release into the United States; and

Whereas, It is the intention of the parties hereto that such cooperation shall be for their mutual benefit and the benefit of the people of the United States.

Now, therefore, for and in consideration of the promises and mutual covenants herein contained, the parties do hereby mutually agree with each other as follows:

PART I—PROVISIONS RELATING TO QUALIFYING ANIMALS FOR ENTRY INTO THE USDA-APPROVED EMBARKATION FACILITY

A. *The Cooperator Agrees:*

1.a. To deposit with the Service upon execution of this Agreement the amount of ——[1] by certified check or money order to cover the cost to the Department for qualifying his animal(s) in the country of origin for entry into the USDA-approved embarkation facility; or

b. To deposit with the Service upon execution of this Agreement a letter of credit from a commercial bank to the Service in the amount of ——[1] consistent with the terms of this Agreement, as determined by the Deputy Administrator, to cover the cost to the Department for qualifying his animal(s) in the country of origin for entry into the USDA-approved embarkation facility.

c. Payment for the costs in Part I incurred by the Cooperator will be due one month (30 days) prior to the day the animals are scheduled for release from the HSTAIC. The letter of credit shall be in effect from the date special authorization is granted to the date the animals are sheduled to be released from the HSTAIC or billings by the Service have been paid. The letter of credit shall be irrevocable for that period except through the mutual consent of the Service and the Cooperator. Billings will be made to the issuer of the letter of credit.

d. Upon execution of this Agreement the Cooperator shall become liable for —— (which represents his prorata share of the fixed costs for qualifying his animal(s) for entry into the USDA-approved embarkation facility) regardless of the disposition of the Cooperator's animal(s). These monies are necessary to qualify the animal(s) for entry into the USDA-approved embarkation facility and to prepare the USDA-approved embarkation facility for receiving animals. The Cooperator shall also be liable for the variable costs and the costs of testing additional animal(s) (see paragraph 2 of Part I) which are actually incurred by the Cooperator in qualifying his animal(s).

2. To pay the actual cost of testing each animal in excess of the number of animals for which special authorization was issued. If these costs exceed the amount of money deposited or covered by letters of credit, a bill for the extra costs incurred, based on official Service accounting records, will be issued to the Cooperator by the Service and is payable upon receipt.

3. To pay for all laboratory tests deemed necessary by the Department to determine freedom from communicable animal diseases in addition to those identified in the Veterinary Services protocol for qualifying the animal(s) for entry into the USDA-approved embarkation facility.

4. To obtain from foreign Government officials any permits or permisssion required so that the Service's personnel will have free access to the approved farm of origin isolation facilities in the country of origin so they can properly assess the safety of the animal(s) regarding exposure to communicable animal diseases during the period the animal(s) are in the country of origin.

5. To obtain from the transporting company any necessary permission for the Service's personnel to accompany the animal(s) from the approved farm of origin to the USDA-approve embarkation quarantine facility.

6. That the eligibility of the animal(s) offered for entrance into the USDA-approved embarkation facility shall be determined by the Service.

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[1] This sum represents the Cooperator's maximum prorata share of the fixed and variable costs to the Department for qualifying the animal(s) into the USDA-approved embarkation facility. This sum was arrived at by applying the following formula:

1. Determine the total number of animal(s) for which special authorization to enter the HSTAIC is being granted to all importers;

2. Determine the established fee per animal, from the applicable published schedule, for the fixed and variable costs of qualifying the number of animal(s) (determined by paragraph 1) into the USDA-approved embarkation facility; and

3. Multiply the established fee per animal (determined by paragraph 2) by the specific number of animal(s) which the Cooperator has received special authorization to enter into the HSTAIC.

B. *The Service Agrees:*

1. To furnish the services of technical and/or professional personnel needed to conduct inspections, perform laboratory procedures, complete examinations, and supervise the isolation, quarantine, and care and handling of the animal(s) being qualified to ensure that they meet the Department's requirements before entering the USDA-approved enbarkation facility.

2. To refund to the Cooperator any part of the fees, above the $1,000 per animal deposit required by 9 CFR 92.41(a)(1), not expended in qualifying the animal(s) to enter the USDA-approved embarkation facility.

PART II—PROVISIONS RELATING TO THE QUARANTINING OF ANIMALS IN THE UDSA-APPROVED EMBARKATION FACILITY AND IN THE HSTAIC

A. *The Cooperator Agrees:*

1.a. To deposit with the Service upon execution of this Agreement the amount of ——[2] by certified check or money order to cover the cost to the Department for quarantining the Cooperator's animal(s) at the USDA-approved embarkation facility and the HSTAIC before their release in the United States, or;

b. To deposit with the Service upon execution of this Agreement a letter of credit from a commercial bank to the Service in the amount of ——,[2] consistent with the terms of this Agreement, as determined by the Deputy Administrator, to cover the cost to the Department for quarantining the Coperator's animal(s) at the USDA-approved embarkation facility and at the HSTAIC.

c. Payment for the costs in Part II incurred by the Cooperator will be due one month (30 days) prior to the day the animals are scheduled for release from the HSTAIC. The letter of credit shall be in effect from the date special authorization is granted to the date the animals are scheduled to be released from the HSTAIC or billings by the Service have been paid. The letter of credit shall be irrevocable for the period except through the mutual consent of the Cooperator and the Service.

d. Upon qualification of any of the Cooperator's animal(s) to enter the USDA-approved embarkation facility, the Cooperator shall become liable for his prorata share[3] of the total fixed costs incurred in quarantining all animals at the USDA-approved embarkation facility and at the HSTAIC, regardless of the disposition of any of the Cooperator's animal(s) at either facility. In no instance shall the Cooperator's liability for the fixed costs per animal at the USDA-approved embarkation facility and at the HSTAIC exceed——(equal to the fixed cost portion of the established fee for quarantining an animal at the USDA-approved embarkation facility and the HSTAIC if only 50 animals qualify for such quarantine). These monies are necessary to prepare the animal(s) for entry into the HSTAIC and to prepare the HSTAIC for receiving and quarantining these animals. The Cooperator shall also be liable for the variable costs actually incurred in quarantining his animal(s).

2. To pay for all laboratory tests deemed necessary by the Department to determine freedom from communicable animal diseases in addition to those identified in the Veterinary Service protocol for qualifying animals in the USDA-approved embarkation facility.

3. To pay the actual cost of treatment of any of the Cooperator's animal(s) which require treatment to be cured of a communicable disease of livestock or poultry while at the USDA-approved embarkation facility or at the HSTAIC. Such payment shall be due upon receipt by the Cooperator of a bill for such treatment from the Service.

4. To obtain from foreign Government officials any permits or permission required to ensure that the Service's personnel will have free access to the USDA-appproved embarkation facility so they can properly assess the safety of the animal(s) regarding exposure to communicable animal diseases during the period the animal(s) are in the USDA-approved embarkation facility.

5. To provide for the maintenance and operation of the USDA-approved embarkation

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[2] This sum represents the Cooperator's maximum prorata share of the fixed and variable costs to the Department for quarantining the Cooperator's animal(s) at the UDSDA-approved embarkation facility and at the HSTAIC. This sum was arrived at by applying the following formula:

1. Determine the established fee per animal from the applicable published schedule, for the fixed and variable costs of quarantining 50 animals in the USDA-approved embarkation facility and in the HSTAIC;

2. Multiply this established fee per animal by the specific number of animal(s) for which the Cooperator has received special authorization to enter into the HSTAIC.

[3] The Cooperator's prorata share is a percentage figure to be determined as follows:

1. Determine the number of special authorizations awarded to the Cooperator which have been filled with animal(s) qualified to enter the USDA-approved embarkation facility; and

2. Divide that number (paragraph 1) by the total number of special authorizations that have been filled by all the importers with animals qualified to enter the USDA-approved embarkation facility.

facility in the foreign country in accordance with approved standards and handling procedures for importation of animals as provided in Part 92 of 9 CFR.

6. All animals which enter the USDA-approved embarkation facility and the HSTAIC will be handled on an "all-in all-out" basis. If any animal in the USDA-approved embarkation facility or the HSTAIC is determined by the Service to be infected with any communicable disease of animals, the remaining animals will be considered to be exposed to such communicable disease.

7. If the Service determines that any of the animals in the USDA-approved embarkation facility are infected with or exposed to foot-and-mouth disease, rinderpest or pleuropneumonia, all animals in that facility shall be refused entry into the HSTAIC and shall be disposed of at the Cooperator's expense. If the Service determines that any of the animals in the HSTAIC are infected with or exposed to foot-and-mouth disease, rinderpest or pleuropneumonia, all such animals in the facility shall be refused entry into the United States and be destroyed in accordance with such conditions as the Deputy Administrator of the Service believes necessary to prevent the dissemination of communicable diseases of animals into the United States.

8. If the Service determines that any of the animals are infected with or exposed to any other communicable disease of animals, such animal shall be treated, if possible, and if cured, become eligible for entry into the United States provided all other requirements under 9 CFR Part 92 are met. However, if it is not possible to treat such animal or if such animal is not cured, then such animal shall be refused entry into the United States and shall be removed from the USDA-approved embarkation facility or the HSTAIC to a country other than the United States within 10 days of the date that the Cooperator is notified by the Service that such animal has been refused entry into the United States. However, at the option of the Cooperator, such animal may be disposed of in accordance with such conditions as the Deputy Administrator of the Service believes necessary to prevent the dissemination of communicable diseases of animals into the United States.

9. The Cooperator is responsible for the risk of loss for the destruction of any animal subject to this Agreement because of being infected with or exposed to any communicable disease of animals or any other loss or damage to the animal.

10. That the eligibility of the animal(s) offered for entrance into the HSTAIC shall be determined by the Service.

11. To obtain from the transporting company any necessary permission for the Service's personnel to accompany a shipment of animal(s) to the HSTAIC.

12. That the eligibility of the animal(s) offered for import into the United States shall be determined by the Service.

B. *The Service Agrees:*

1. To furnish the services of technical and/or professional personnel needed to conduct inspection, perform laboratory procedures, complete examination, and supervise the isolation, quarantine, and care and handling of animals being imported to ensure that they meet the Department's quarantine requirements at the USDA-approved embarkation facility and the HSTAIC before release into the United States.

2. To refund to the Cooperator any part of the fees not expended at the USDA-approved embarkation facility and the HSTAIC on a per animal basis.

PART III

C. *It Is Mutually Understood and Agreed That:*

1. During the performance of this cooperative work, the Cooperator agrees to be bound by the Equal Opportunity and Nondiscrimination provisions as set forth in Exhibit B and Nonsegregation of Facilities provisions as set forth in Exhibit C, which are attached hereto and made a part hereof.

2. No member of or delegate to Congress or resident commissioner, shall be admitted to any share or part of this Agreement or to any benefit to arise therefrom; but this provision shall not be construed to extend to the Agreement if made with a corporation for its general benefit.

3. Part I of this Agreement shall become effective upon date of final signature and shall continue until final settlement of all matters relevant to the period for qualifying animal(s) on the premises of origin in the country of export for entry into the USDA-approved embarkation facility, as determined by the Service.

4. Part II of this Agreement shall become effective upon date of final signature and shall continue until final settlement of all matters relevant to the quarantine periods at the USDA-approved embarkation facility and the HSTAIC, as determined by the Service; *Provided however,* That if less than a total of 50 animals qualify for entry into the USDA-approved embarkation facility, the quarantine period for all animals shall be cancelled at the USDA-approved embarkation facility and at the HSTAIC and both parties shall be released from the provisions in Part II.

5. This Agreement may be amended by agreement of the parties in writing. It may be terminated by either party upon 30 days' written notice to the other party.

Date ____________________

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Cooperator,

Date ——————————————

———————————————————
Director, NPPS, VS.

(e) *Water buffalo from Trinidad.* Notwithstanding the other provisions of this section, one shipment of approximately 140 water buffalo from Trinidad may be imported into the United States through HSTAIC in 1981 in compliance with the requirements in §§ 92.12(b), 92.27 and 92.28 applicable to importations of ruminants from countries of Central America and the West Indies.

(f) *Llamas and alpacas from Chile.* One shipment of approximately 350 llamas and alpacas from Chile may be imported into the United States through HSTAIC in 1984 in accordance with paragraphs (c) and (d) of this section; *Except That* there shall be two series of laboratory tests instead of the three series of laboratory tests referred to in paragraph (c)(3)(iv) of this section; and the provisions relating to qualifying animals for entry into the USDA-approved embarkation quarantine facility shall not apply, and the fee schedule shall be furnished to the importers but not published. Notwithstanding the provisions of § 92.42, the USDA-approved embarkation quarantine facility for this importation of llamas and alpacas shall be located in Arica, Chile. Otherwise, provisions of § 92.42 shall be applicable to the importation of these llamas and alpacas.

[28 FR 5971, June 13, 1963. Redesignated and amended at 44 FR 10054, Feb. 16, 1979; 44 FR 12958, Mar. 9, 1979; 45 FR 7779, Feb. 5, 1980; 45 FR 29269, May 5, 1980; 45 FR 85723, Dec. 30, 1980; 46 FR 24931, May 4, 1981; 46 FR 46786, Sept. 22, 1981; 46 FR 52088, Oct. 26, 1981; 47 FR 22080, May 21, 1982; 48 FR 32970, July 19, 1983; 49 FR 5727, Feb. 15, 1984; 49 FR 20644, May 16, 1984; 49 FR 22769, June 1, 1984; 49 FR 32842, Aug. 17, 1984]

§ 92.42 Embarkation quarantine facility; criteria and standards for approval.

Criteria for the establishment of an approved embarkation quarantine facility outside the United States for the purpose of importing animals into the United States through the Harry S Truman Animal Import Center are as follows:

(a) *Establishment.* (1) The Deputy Administrator, Veterinary Services, may enter into an agreement with one or more parties for the establishment of such a facility pursuant to the standards in paragraph (b) of this section.

(2) To qualify for designation as an approved embarkation quarantine facility and to retain such approval, the physical facility, and its maintenance and operation, shall meet the minimum requirements of paragraph (b) of this section.

(3) All costs associated with the establishment and operation of such an approved embarkation quarantine facility shall be borne by the owner or operator of such facility.

(4) Requests for approval and plans for proposed facilities shall be submitted to the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782. Each request for approval of a facility will be considered on the basis of the date and time it is received by the Deputy Administrator, Veterinary Services and the geographical location of the facility. The Department shall approve only one facility to service a continent. The first such application per continent which can comply with the standards and regulations established in this section shall be approved by the Deputy Administrator, Veterinary Services. The first such application received which can comply with the standards and regulations established in this section shall be approved by the Deputy Administrator, Veterinary Services. If the approval of any approved facility is ever terminated or revoked, then the Deputy Administrator, Veterinary Services, shall approve another application in the same manner as set forth in this paragraph.

(5) Permission to place animals in the foreign embarkation facility shall be given to any person who has received permission to import animals through the Harry S Truman Animal Import Center unless the Deputy Administrator, Veterinary Services, determines that sufficient grounds exist

whereby such person may be denied such permission.

(6) Fees charged by the owner or operator for the use of such facility shall be provided in private agreements between the owner or operator of the facility and the owners of the animals proposed for importation. Such fees shall be nondiscriminatory and reasonable as determined by the Deputy Administrator, Veterinary Services.

(7) Approval of any approved quarantine facility may be withdrawn at any time by the Deputy Administrator, Veterinary Services, upon his determination that any requirement of this section is not being met. Before such action is taken, the operator of the facility will be informed of the reasons for the proposed action and afforded opportunity to present his views thereon. Upon withdrawal of approval, the operator, upon request, shall be afforded opportunity for a hearing with respect to the merits or validity of such action; but such withdrawal or refusal shall continue in effect unless otherwise ordered by the Deputy Administrator, Veterinary Services.

(b) *Standards for approval of embarkation quarantine facilities*—(1) *Location.* (i) The embarkation quarantine facility shall be so located as to be isolated from all domestic ruminants, swine, and poultry and from all wild ruminants, swine, and poultry and shall be near docks from which international shipments may be made by ocean vessels.

(ii) The route of travel between the embarkation quarantine facility and the docks from which such animals are to be exported shall be through areas free of domestic and wild ruminants, swine and poultry.

(iii) The facility shall be so situated that there will be no contact between animals held in the facility with any other species of animals.

(iv) The facility shall be so situated that it will be free from contact with water and waste effluents from local livestock or poultry. Water and waste effluents from the facility shall be disposed of in a manner determined by the Deputy Administrator, Veterinary Services, to be adequate to insure no exposure to local livestock or poultry.

(2) *Building.* (i) The exterior of the building shall be of durable low maintenance, waterproof type construction that will withstand repeated cleaning and disinfecting.

(ii) Roofs shall be watertight. The styling and configuration of the roof of the animal holding building shall provide for optimum air circulation throughout the facility.

(iii) The interior finish of the building shall be durable, washable, and of low maintenance type construction. The floor shall be concrete with no cracks or crevices.

(iv) All openings in the building shall be double screened with such mesh as to preclude the entrance of small flying insects such as mosquitos into the animal holding area. There shall be a program of insect vector control established by Veterinary Services if the cattle are removed from the double screened building any time prior to export to the Harry S Truman Animal Import Center or in any other circumstance when it is determined by the USDA Veterinarian in Charge of the quarantine operation that insects which may transmit communicable animal diseases are entering the animal holding area. Such insect vector control program shall include the treatment of animals, building interiors and the areas around the buildings with pesticides registered by the United States Environmental Protection Agency for such use and in accordance with its labeling, and approved by the national government of the country in which the facility is located.

(v) Stalls, pens, and runways shall be constructed of sufficient height and strength to confine and restrain all animals simultaneously for daily veterinary examinations.

(vi) At least 70-foot candle lighting shall be provided in the inspection area. A minimum light of 30-candle shall be available in all other areas of the facility.

(vii) A dipping vat of a concrete pit type with inspection chute, holding pen, dripping pen, and post-drip area similar to USDA Extension Plan 5940, revised, shall be provided.[10]

(viii) The waste management system shall be carefully designed to meet all applicable sanitation and quarantine requirements and the existing environmental standards of the country in which the embarkation quarantine facility is located.

(3) *Fencing.* (i) The outer perimeter of all facilities shall be surrounded by a fence which shall be of sufficiently small mesh as to preclude the entrance of small farm animals, including dogs, and of such height and strength as to prevent entrance of larger animals. This fence shall be located at least 200 feet from the building in which quarantined animals are to be held, except that, in an urban or industrial area the location of the fence may be less than 200 feet as determined by the Deputy Administrator, if such action will not increase the risk that communicable diseases of livestock or poultry will be disseminated from the facility.

(ii) In areas affected by cattle fever ticks all such facilities shall be double fenced with the inner perimeter fence located at least 15 feet from the outer perimeter fence. When double fencing is required, the space between the outer and inner perimeter fences shall be kept free from all foliage at all times.

(iii) The outer fence of the facility shall be posted with signs in appropriate language, which shall convey the following: Restrictd Area—Keep Out, Quarantine Area—Keep Out, or Registered Quarantine Area—Keep Out.

(4) *Other requirements.* (i) Access into the quarantine area shall be through a single door which shall lead into a walkthrough shower area with clothes change areas located on either side of the shower and adjacent thereto.

(ii) Toilet and lavatory facilities as determined by the Deputy Administrator, Veterinary Services, to be adequate to preclude transmission of livestock or poultry disease agents from the facility shall be located within the animal holding areas.

(iii) A sufficient supply of clean clothing including towels and footwear as determined by the Deputy Administrator to be adequate to prevent the transmission of livestock or poultry disease agents from the facility, shall be maintained within the quarantine area.

(iv) A continuous supply of hot and cold running water shall be provided which shall include potable water for personnel.

(v) If lunch is to be eaten within the facility, a lunch room must be provided and all food entered into the facility must be approved by the supervising United States government veterinarian.

(vi) A separate room containing the equipment for preparation and packaging of laboratory specimens with adequate office space as determined by the Deputy Administrator, Veterinary Services, to perform his duties shall be provided for the supervising veterinary official. All records, equipment, and other materials used in the facility, must be maintained within the quarantine facility for the entire quarantine period.

(vii) A separate area situated apart from the animal holding area shall be provided for necropsies and a means for the removal of the carcasses of dead animals shall be provided without breaking quarantine security.

(viii) An animal receiving area and a chute or stocks for restraint during examination and veterinary inspection, as determined to be appropriate by the Deputy Administrator, Veterinary Services, to permit examination of the animal, shall be provided.

(ix) Feed shall be stored in such a manner that replenishment during the quarantine period does not require transporting vehicles to enter the quarantine area.

(x) Equipment necessary for the care, cleaning, feeding, waste disposal, and handling of the animals shall be provided and maintained within the quarantine area.

(xi) Additional requirements as to security, physical plant and facilities, and sanitation may be imposed by the Deputy Administrator, Veterinary Services, in each specific case in order to assure that the quarantine of the animals in such facility will be adequate to enable determination of their health status, prevent the spread of disease among animals in quarantine, and prevent escape of animal disease agents from the facility.

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[10] Copies of the USDA Extension Plan 5940, revised, may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, Hyattsville, Maryland 20782.

[42 FR 37969, July 26, 1977. Redesignated and amended at 44 FR 10056, Feb. 16, 1979; 44 FR 19374, Apr. 3, 1979; 45 FR 70224, Oct. 23, 1980]

§ 92.43 Cattle from the Republic of Ireland.

(a) All cattle to be imported from the Republic of Ireland shall be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Republic of Ireland showing that the cattle originated from a herd which is officially certified by the Republic of Ireland as a brucellosis qualified for export herd and that the cattle meet the requirements in § 92.43(c).

(b) A brucellosis qualified for export herd is a herd in which all of the cattle have been maintained as a herd unit for at least two years prior to importation and all of the test eligible cattle in the herd (i.e., cattle over 6 months of age, except steers and spayed heifers) have been tested annually for brucellosis and found negative in accordance with Republic of Ireland requirements for at least two years prior to importation. The most recent negative herd test must have been conducted within 12 months of the date of importation. In addition:

(1) Such herd unit may include cattle which were born and raised within such herd unit during the two year period, or cattle which were moved directly to the herd from another herd unit of like status; or

(2) Such herd unit may include other cattle (except brucellosis reactors, suspects and animals listed in § 92.43(c)(1)) if:

(i) Such other cattle have been tested for brucellosis and found negative within 30 days prior to entry into the herd unit and all eligible cattle in the herd unit have been tested for brucellosis and found negative not less than 90 days following the date when the last of the other cattle had been added to the herd unit; or

(ii) All eligible cattle in the herd unit have been tested negative for brucellosis no less than 180 days nor more than 12 months (365 days) following the date when the last of the other cattle had been added to the herd unit.

(c) The certificate accompanying cattle offered for importation from the Republic of Ireland shall show that the cattle are from a brucellosis qualified for export herd and that they meet the following requirements:

(1) The cattle to be exported were not born to or nursed by brucellosis reactors and they were not born in a herd at the time the herd was under quarantine due to brucella infection.

(2) The cattle were placed in an isolation facility approved by a full-time, salaried, Government of Ireland veterinary official, on separate premises a minimum of 500 yards from other livestock not destined for export to the United States for at least 60 days prior to export.

(3) The cattle were negative to the following tests conducted not less than 60 nor more than 120 days from the date of export and a second set of tests conducted within 30 days of the date of export:

(i) Plate or Tube agglutination test conducted in dilutions to detect reactions at 30, 60, 120, and 240 International Units per milliliter (IU/ml);

(ii) Brucellosis card test (Rose Bengal test); and

(iii) Complement Fixation (CF) test conducted in dilutions to detect prozone reactions, when present.

(4) Cattle are eligible for entry only if classified as negative at 30 IU to the Plate or Tube agglutination test, negative to the brucellosis card test and negative to the CF test as performed and interpreted by standard methods at the Republic of Ireland Brucellosis Diagnostic Laboratory. Any animal exhibiting a prozone serological reaction is ineligible for export to the United States.

(5) Cattle showing a serological titer more than 60 IU to the Plate or Tube agglutination test, or a reaction to the Brucellosis card test (Rose Bengal) or

CF test that would be interpreted to be an infected animal (reactor) under the Republic of Ireland brucellosis control program. Animals form that herd of origin and all other cattle having the opportunity for contact with the reactor animal shall not be eligible for export to the United States. Brucellosis bacteriologically positive animals, if known, regardless of serologic reactions, are not eligible for importation nor are any animals in contact with such animals.

(6) The cattle were moved directly to the port of export from the isolation facility without contact with any other cattle which are not qualified for export to the United States.

(d) The certificate accompanying the cattle offered for importation must also show the dates and places of testing, names of the consignor and consignee, and descriptions of the cattle, including breed, ages, markings, and tattoo and eartag numbers.

[47 FR 49345, Nov. 1, 1982]

PART 93—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER CERTAIN ACTS

Subpart A—General

Sec.

93.1 Scope and applicability of rules of practice.

Subpart B—Supplemental Rules of Practice

93.10 Stipulations.

AUTHORITY: Secs. 3, 4, 5, and 7, 23 Stat. 32, as amended; secs. 6, 26 Stat. 416, as amended; secs. 7 and 8, 26 Stat. 416; sec. 10, 26 Stat. 417; secs. 2 and 3, 32 Stat. 792, as amended; secs. 3 and 4, 76 Stat. 130; sec. 6, 76 Stat. 131, as amended; sec. 11, 76 Stat. 132; secs. 1 and 2, 84 Stat. 202; 21 U.S.C. 102-105, 111, 112, 114a, 117, 120, 122, 134b, 134c, 134e, 134f, 135, 135a; 7 CFR 2.17, 2.51, 371.2(d).

SOURCE: 48 FR 30095, June 30, 1983, unless otherwise noted.

Subpart A—General

§ 93.1 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the Department of Agriculture promulgated in Subpart H of Part 1, Subtitle A, Title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings under the following statutory provisions:

Act of May 29, 1884, commonly known as the Animal Industry Act, Section 7, as amended (21 U.S.C. 117),

Act of August 30, 1890, Section 6, as amended (21 U.S.C. 104),

Act of February 2, 1903, commonly known as the Cattle Contagious Diseases Act of 1903, Section 3, as amended (21 U.S.C. 122),

Act of July 2, 1962, Section 6(a), as amended (21 U.S.C. 134e),

Act of May 6, 1970, Section 2, as amended (21 U.S.C. 135a).

In addition, the Supplemental Rules of Practice set forth in Subpart B of this part shall be applicable to such proceedings.

Subpart B—Supplemental Rules of Practice

§ 93.10 Stipulations.

(a) At any time prior to the issuance of a complaint seeking a civil penalty under any of the Acts listed in § 93.1, the Administrator, in his discretion, may enter into a stipulation with any person in which:

(1) The Administrator or the Administrator's delegate gives notice of an apparent violation of the applicable Act, or the regulations issued thereunder, by such person and affords such person an opportunity for a hearing regarding the matter as provided by such Act;

(2) Such person expressly waives hearing and agrees to pay a specified penalty within a designated time; and

(3) The Administrator agrees to accept the penalty in settlement of the particular matter involved if the penalty is paid within the designated time.

(b) If the penalty is not paid within the time designated in such a stipulation, the amount of the stipulated penalty shall not be relevant in any respect to the penalty which may be assessed after issuance of a complaint.

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), NEWCASTLE DISEASE (AVIAN PNEUMOENCEPHALITIS), AFRICAN SWINE FEVER, AND HOG CHOLERA: PROHIBITED AND RESTRICTED IMPORTATIONS

Sec.

94.1 Designation of countries where rinderpest or foot-and-mouth disease exists; importations prohibited.
94.1a Criteria for determining the separate status of a territory or possession as to rinderpest and foot-and-mouth disease.
94.2 Fresh, chilled, or frozen products (other than meat), and milk and milk products of ruminants and swine.
94.3 Organs, glands, extracts, or secretions of ruminants or swine.
94.4 Foreign cured or cooked meats from countries where rinderpest or foot-and-mouth disease exists.
94.5 Garbage; regulations on storage and movement on certain means of conveyance.
94.6 Carcasses of poultry, game birds, and other birds, parts or products thereof, and eggs other than hatching eggs; restrictions, exceptions.
94.7 Disposal of animals, meats, and other articles ineligible for importation.
94.8 Pork and pork products from countries where African swine fever exists or is reasonably believed to exist.
94.9 Pork and pork products from countries where hog cholera exists.
94.10 Swine from countries where hog cholera exists; importations prohibited.
94.11 Restrictions on importation of meat and other animal products from specified countries.
94.12 Pork and pork products from countries where swine vesicular disease exists.
94.13 Restrictions on importation of pork or pork products from specified countries.
94.14 Swine from countries where swine vesicular disease exists; importation prohibited.
94.15 Animal products and materials; movement and handling.
94.16 Milk and milk products.

AUTHORITY: 7 U.S.C. 147a, 150ee, 161, 162, 450; 19 U.S.C. 1306, 21 U.S.C. 111, 114a, 134a, 134b, 134c, and 134f; 42 U.S.C. 4331, 4332; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 28 FR 5980, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24926, Dec. 24, 1971.

§ 94.1 Designation of countries where rinderpest or foot-and-mouth disease exists; importations prohibited.

(a) Notice is hereby given that, in accordance with section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), it has been determined, and official notice has been given to the Secretary of the Treasury that:

(1) Rinderpest or foot-and-mouth disease exists in all countries of the world, except those listed in paragraph (a)(2) of this section;

(2) The following countries are declared to be free of both rinderpest and foot-and-mouth disease: Australia, Bahama Islands, Barbados, Bermuda, British Honduras (Belize), Canada, Channel Islands, Denmark, Finland, Great Britain (England, Scotland, Wales, and Isle of Man), Greenland, Guatemala, Haiti, Honduras, Iceland, Ireland, Jamaica, Japan, Costa Rica, Dominican Republic, El Salvador, Fiji, Mexico, New Zealand, Nicaragua, Northern Ireland, Norway, Panama, Panama Canal Zone, Territory of St. Pierre and Miquelon and Sweden, Tobago, Trinidad, and Trust Territory of the Pacific Islands.

(b) The bringing within the territorial limits of the United States of cattle, sheep, or other ruminants, or swine, or of fresh, chilled, or frozen meat of such animals (including such animals or meat on board a vessel or other means of conveyance for use as sea stores or otherwise), which originate in or are shipped from a country designated in paragraph (a) of this section as a country infected with rinderpest or foot-and-mouth disease or which enter a port in or otherwise transit such a country, is prohibited, except as provided in Part 92 of this chapter for wild ruminants and wild swine, and except as provided in paragraph (c) of this section for meat.

(c) Except as otherwise provided in this part, fresh, chilled, or frozen meat of ruminants or swine which originates in and is shipped from a country other than those designated in paragraph (a) of this section as infected with rinderpest or foot-and-mouth disease and which enters any port of such an infected country or otherwise transits such an infected country en route to the United States, may be imported into the United States insofar as the restrictions of this part are concerned, if:

(1) The meat is accompanied by the foreign meat inspection certificate or certificates required under § 327.6 of Chapter III of this title;

(2) The hold or compartment of the transporting carrier into which the meat was loaded was sealed in the country of origin by an official of such country with seals approved by the Veterinary Services unit of the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture, so as to prevent contamination, and the loading of any cargo into and the removal of any cargo from such sealed hold or compartment, en route to the United States;

(3) The seals used to seal such hold or compartment of such carrier are serially numbered and recorded on the certificate or certificates, referred to in paragraph (c)(1) of this section accompanying the shipment;

(4) Upon arrival of the carrier in the United States port of entry the seals are found by a representative of Veterinary Services of this Department to be intact and such representative finds that there is no evidence indicating that the seals were tampered with; and

(5) Such meat is found by a representative of this Department to be as represented in the certificate or certificates referred to in paragraph (c)(1) of this section.

(Approved by the Office of Management and Budget under control number 0579-0015)

[30 FR 12118, Sept. 23, 1965]

EDITORIAL NOTE: For Federal Register citations affecting § 94.1, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 94.1a Criteria for determining the separate status of a territory or possession as to rinderpest and foot-and-mouth disease.

(a) The Secretary of Agriculture will make a determination as to whether a territory or possession may be deemed separate from the mother country, in which rinderpest or foot-and-mouth disease has been determined to exist, for the purposes of section 306(a) of the Act of June 17, 1930, as amended (19 U.S.C. 1306(a)), only if:

(1) The official authority of that territory or possession, having responsibility for animal health matters, has declared such territory or possession free of rinderpest and foot-and-mouth disease;

(2) The territory or possession is geographically separate from the mother country and has full autonomy from the mother country in all animal health matters, including import and export;

(3) The territory or possession has a veterinary service which is capable of speedily detecting rinderpest or foot-and-mouth disease and which is comprised of veterinarians who:

(i) Are employed as officials of the government of the territory or possession,

(ii) Are graduates of a recognized school of veterinary medicine, and

(iii) Are assigned in sufficient numbers and are so distributed, with respect to the livestock population, to be able to promptly recognize the existence of rinderpest and foot-and-mouth disease;

(4) A laboratory capable of diagnosing rinderpest and foot-and-mouth disease is available to the veterinary service of the territory or possession;

(5) Vaccinations for foot-and-mouth disease or rinderpest are not permitted in the territory or possession;

(6) The reporting of rinderpest or foot-and-mouth disease to the veterinary authorities of the territory or possession is required by anyone who has notice of the existence of these diseases;

(7) Laws and regulations are in effect and are administered in such manner as to insure against the introduction of foot-and-mouth disease or rinderpest through the importation of animals, meat, and animal products from countries, including the mother country, declared by the United States Secretary of Agriculture to be countries where foot-and-mouth disease or rinderpest exist;

(8) Animals introduced into the territory or possession from rinderpest or foot-and-mouth disease infected countries, including the mother country,

are imported through a quarantine station and under conditions acceptable to the Secretary of Agriculture of the United States, and such conditions include, but are not restricted to:

(i) Tests deemed necessary for the detection of rinderpest and foot-and-mouth disease,

(ii) Quarantine deemed necessary for the detection of rinderpest and foot-and-mouth disease, and

(iii) Opportunity for observation by a United States Department of Agriculture veterinarian during all phases of the import procedures;

(b) An on-site inspection by a veterinary representative of the United States Department of Agriculture to determine whether the criteria in this section are met shall be made of the territory or possession before any final determination is made as to its status.

[39 FR 13069, Apr. 11, 1974]

§ 94.2 Fresh, chilled, or frozen products (other than meat), and milk and milk products of ruminants and swine.

(a) The importation of fresh, chilled, or frozen products (other than meat and milk and milk products) derived from ruminants or swine, originating in, shipped from, or transiting any country designated in § 94.1(a) as a country infected with rinderpest or foot-and-mouth disease is prohibited, except as provided in § 94.3 and Parts 95 and 96 of this chapter.

(b) The importation of milk and milk products of ruminants and swine originating in, shipped from, or transiting any country designated in § 94.1(a) as a country infected with rinderpest or foot-and-mouth disease is prohibited, except as provided in § 94.16.

[40 FR 44123, Sept. 25, 1975]

§ 94.3 Organs, glands, extracts, or secretions of ruminants or swine.

The importation of fresh, chilled, or frozen organs, glands, extracts, or secretions derived from ruminants or swine, originating in any country designated in § 94.1, except for pharmaceutical or biological purposes under conditions prescribed by the Deputy Administrator, Veterinary Services in each instance, is prohibited.

§ 94.4 Foreign cured or cooked meats[1] from countries where rinderpest or foot-and-mouth disease exists.

(a) The importation of cured meats derived from ruminants or swine, originating in any country designated in § 94.1 is prohibited unless the following conditions have been fulfilled:

(1) All bones shall have been completely removed in the country of origin.

(2) The meat shall have been held in an unfrozen, fresh condition for at least 3 days immediately following the slaughter of the animals from which it was derived.

(3)(i) The meat shall have been thoroughly cured and fully dried in such manner that it may be stored and handled without refrigeration, as in the case of salami and other summer sausages, tasajo, xarque, or jerked beef, bouillon cubes, dried beef, and Westphalia, Italian and similar type hams. The term "fully dried" as used in this paragraph means dried to the extent that the water-protein ratio in the wettest portion of the product does not exceed 2.25 to 1.

(ii) Laboratory analysis of samples to determine the water-protein ratios will not be made in the case of all shipments of cured and dried meats. However, in any case in which the inspector is uncertain whether the meat complies with the requirements of paragraph (a)(3)(i) of this section, he will send a sample of the meat representative of the wettest portion to the Meat Inspection Division for analysis of the water-protein ratio. Pending such analysis the meat shall not be released or removed from the port of entry.

(b) The importation of cooked meats derived from ruminants or swine originating in any country designated in § 94.1 is prohibited unless the following conditions shall have been fulfilled:

(1) All bones shall have been completely removed in the country of origin.

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[1] This does not include any meat that has been sterilized by heat in hermetically sealed containers.

(2) The meat shall have been heated to such an extent that, upon inspection, the meat will have a thoroughly cooked appearance throughout.

(3) When so directed by the Deputy Administrator, Veterinary Services, such meat shall be consigned directly from the port of entry to a meat-processing establishment operating under Federal meat inspection that has been approved by him for the further processing of such meat. Such meat shall be shipped from the port of entry to the approved establishment under Customs seals or seals of Veterinary Services and shall be otherwise handled as the said Deputy Administrator, Veterinary Services may direct. Seals applied under authority of this section shall not be broken except by persons authorized to do so by the said Deputy Administrator, Veterinary Services.

§ 94.5 Garbage; regulations on storage and movement on certain means of conveyance.

(a) Garbage which is on or unloaded from any means of conveyance arriving in the places listed below is subject to general surveillance for compliance with this section by Animal and Plant Health Inspection Service inspectors and to such disposal measures as authorized by section 105 of the Federal Plant Pest Act (7 U.S.C. 150dd), section 10 of the Plant Quarantine Act of 1912, as amended (7 U.S.C. 164a), section 2 of the act of February 2, 1903, as amended (21 U.S.C. 111), and section 306 of the act of June 17, 1930, as amended (19 U.S.C. 1306), to prevent the dissemination of plant pests and livestock or poultry diseases:

(1) The United States from any place outside thereof (except garbage derived from stores obtained only in the continental United States or Canada on board vessels or aircraft that move solely between continental United States ports or between continental United States ports and Canadian ports);

(2) The continental United States from Hawaii or any territory or possession;

(3) Any territory or possession from any other territory or possession or from Hawaii; or

(4) Hawaii from any territory or possession.[3]

(b)(1) All garbage regulated in paragraph (a) of this section shall be contained in tight, leak-proof covered receptacles (inside the guard rail on vessels) during storage on board such means of conveyance while in the territorial waters or otherwise within the territory of the United States. Such garbage shall not be unloaded from such means of conveyance in the United States unless such garbage is removed in tight, leak-proof receptacles under the direction of an Animal and Plant Health Inspection Service inspector to an approved facility for incineration, sterilization, or grinding into an approved sewage system, under supervision by such an inspector, or such garbage is removed for other handling in such manner and under such supervision as may, upon request in specific cases, be approved by the Administrator as complying with the applicable laws for environmental protection and as adequate to prevent the dissemination into or within the United States of plant pests and livestock or poultry diseases.

(2) Application for approval of a facility or sewage system may be made in writing by the authorized representative of any carrier or by the official having jurisdiction over the port or place of arrival of the means of conveyance, to the Administrator, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250. The application shall be endorsed by the operator of the facility or sewage system. Approval will be granted if the Administrator determines that the requirements set forth in this section are met. Approval may be denied or withdrawn at any time, if the Administrator determines that such requirements are not met, after notice of the proposed denial or withdrawal of the approval and the reasons therefor, and an opportunity to demonstrate or achieve

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[3] The provisions of this section for handling of garbage do not relieve any prohibition or restriction elsewhere in this title on bringing any meat or other product or article into the United States or on the interstate movement of any product or article.

compliance with such requirements, has been afforded to the operator of the facility or sewage system and to the applicant for approval. However, approval may also be withdrawn without such prior procedure in any case in which the public health, interest or safety requires immediate action, and in such case, the operator of the facility or sewage system and the applicant for approval shall promptly thereafter be given notice of the withdrawal and the reasons therefor and an opportunity to show cause why the approval should be reinstated.

(c) The Plant Protection and Quarantine Programs and Veterinary Services, Animal and Plant Health Inspection Service, will cooperate with other Federal, State, and local agencies responsible for enforcing other statutes and regulations governing disposal of garbage to the end that such disposal shall be adequate to prevent the dissemination of plant pests and livestock or poultry diseases and comply with applicable laws for environmental protection. The inspectors, in maintaining surveillance over garbage movements and disposal, shall coordinate their activities with the activities of representatives of the Environmental Protection Agency and other Federal, State, and local agencies also having jurisdiction over such garbage.

(d) As used in this section:

(1) "Garbage" means all waste material derived in whole or in part from fruits, vegetables, meats or other plant or animal (including poultry) material, and other refuse of any character whatsoever that has been associated with any such material on board any means of conveyance, and including food scraps, table refuse, galley refuse, food wrappers or packaging materials, and other waste material from stores, food preparation areas, passengers' or crews' quarters, dining rooms, or any other areas on vessels, aircraft, or other means of conveyance.

(2) "Sterilization" means cooking garbage at 212° F. for 30 minutes and disposal of the residue by burying in a landfill, except that the burial provisions do not apply to materials extracted from the residue after cooking and determined by the Administrator to be unsuitable for use as food or as soil additives.

(3) "Incineration" means to reduce the garbage to ash by burning.

(4) "Approved sewage system" means a sewage system approved by the Administrator, Animal and Plant Health Inspection Service, upon his determination that the system is designed and operated in such a way as to preclude the discharge of sewage effluents onto land surfaces or into lagoons or other stationary waters, and otherwise is adequate to prevent the dissemination of plant pests and livestock or poultry diseases, and that it is certified by an appropriate government official as currently complying with the applicable laws for environmental protection.

(5) "Approved facility" means a facility approved by the Administrator, Animal and Plant Health Inspection Service, upon his determination that it has equipment and uses procedures that are adequate to prevent the dissemination of plant pests and livestock or poultry diseases, and that it is certified by an appropriate government official as currently complying with the applicable laws for environmental protection.

(6) "Carrier" means the principal operator of a means of conveyance.

(7) "United States" means the States, District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands of the United States.

(8) "Territories or possessions" means Guam, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands of the United States.

(9) "Continental United States" means the 49 States located on the continent of North America and the District of Columbia.

(Approved by the Office of Management and Budget under control number 0579-0015)

[39 FR 32323, Sept. 6, 1974, as amended at 43 FR 39956, Sept. 8, 1978; 45 FR 80269, Dec. 4, 1980; 48 FR 57472, Dec. 30, 1983]

§ 94.6 Carcasses of poultry, game birds, and other birds, parts or products thereof, and eggs other than hatching eggs; restrictions, exceptions.

(a)(1) Viscerotropic velogenic Newcastle disease is considered to exist in all countries of the world except those listed in paragraph (a)(2) of this section.

(2) The following countries are considered to be free of viscerotropic velogenic Newcastle disease: Australia, Canada, Denmark, Finland, Great Britain (England, Scotland, Wales, and the Isle of Man), Iceland, New Zealand, Northern Ireland, Norway, Republic of Ireland, and Sweden.

(b) For the purposes of this section, the following terms shall mean:

(1) *Infected country.* Any country not listed in paragraph (a)(2) of this section as free of viscerotropic velogenic Newcastle disease.

(2) *Poultry.* Chickens, turkeys, swans, pheasants, grouse, partridges, quail, guinea fowl, pea fowl, and the non-migratory types of ducks, geese, pigeons and doves.

(3) *Birds.* All members of the class Aves (other than poultry or game birds).

(4) *Game Birds.* Migratory types of birds such as ducks, geese, pigeons and doves. ("Migratory" refers to flight to and from the United States in accordance with a seasonal pattern.)

(5) *Thoroughly cooked.* A carcass or any part or product thereof which has been heated so that its flesh and jucies have lost all red or pink color.

(c) Any carcasses of poultry, game birds, and other birds, or parts or products thereof, which originated in and were shipped directly from a country listed in paragraph (a)(2) of this section are exempt from the requirements of this section.

(d) Any carcasses of poultry, game birds, and other birds, or parts or products thereof, which originated in any infected country or which transited any such country may be imported only in accordance with the following requirements:

(1) Carcasses of game birds and carcasses of free-flying quail (as opposed to commerical, domestic or pen-raised quail) may be imported if they have been eviscerated and the heads and feet removed.

(2) Carcasses, or parts or products of carcasses, of poultry, game birds, and other birds may be imported for consignment to any museum, educational institution or other establishment which has provided the Deputy Administrator, Veterinary Services, with evidence that it has the equipment, facilities, and capabilities to store, handle, process, or disinfect such articles so as to prevent the introduction or dissemination of viscerotropic velogenic Newcastle disease into the United States, and which is approved by him.[3]

(3) Carcasses, or parts or products of carcasses, of poultry, game birds, and other birds, may be imported if packed in hermetically sealed containers and if cooked by a commercial method after such packing to produce articles which are shelf stable without refrigeration.

(4) Carcasses, or parts or products of carcasses, of poultry, game birds, and other birds may be imported if thoroughly cooked, and if, upon inspection by a representative of the United States Department of Agriculture at the port of entry, the carcasses or parts or products thereof have a thoroughly cooked appearance throughout.

(e) Carcasses or parts or products of carcasses, of poultry, game birds, and other birds which do not qualify for importation under paragraph (c) or (d) of this section may be imported only if the importer applies to, and is granted a permit by, the Deputy Administrator, Veterinary Services authorizing such importation. Permission will be given only when the Deputy Administrator determines that such importation will not constitute a risk of introduction or dissemination of viscerotropic velogenic Newcastle disease into the United States.

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[3] Information as to the identity of approved establishments may be obtained from, and request for approval of any establishment may be made to, the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250. Establishments will be approved only if the Deputy Administrator, Veterinary Services, determines that the imported articles will be so handled at the establishments as to prevent the introduction or dissemination of viscerotropic velogenic Newcastle disease into the United States. Approval of any establishment may be refused or withdrawn only after the operator thereof has been given notice of the proposed action and has had an opportunity to present his views thereon.

(f) Eggs, other than hatching eggs,[4] of poultry, game birds, and other birds, originating in and shipped directly from a country listed in paragraph (a)(2) of this section are exempt from the requirements of this section.

(g) Except as provided in paragraph (h) of this section, eggs, other than hatching eggs[4] of poultry, game birds, and other birds, originating in or transiting an infected country may be imported only if:

(1) The eggs are accompanied by a certificate signed by a salaried veterinary officer of the national government of the country of origin stating:

(i) That the flock or flocks of origin were found upon inspection to be free from evidence of communicable disease of poultry;

(ii) That no Newcastle disease has occurred on the premises of origin or on adjoining premises during the 90 days immediately preceding the date of movement of the eggs from such country.

(iii) That insofar as it has been possible to determine, the flock or flocks of origin were not exposed to Newcastle disease during the 90 days immediately preceding the date of movement of the eggs from such country;

(iv) That the eggs have been washed and sanitized in a hypochlorite solution of from 100 p.p.m. to 200 p.p.m. of available chlorine and are packed in new, unused packing materials.

(v) That the eggs are from flocks determined to be free of Newcastle disease and other communicable diseases of poultry as demonstrated through a surveillance program in effect for not less than 60 days before such eggs are certified for exports to the United States, with such surveillance maintained during the period in which the eggs being certified were laid.

(2) The surveillance program required under paragraph (g)(1)(v) of this section shall be one of the following:

(i) Placement of Newcastle disease susceptible sentinel birds[5] in the flock or flocks of origin at a rate of not less than one sentinel bird per thousand, with a minimum of 30 sentinel birds per house, with the sentinels remaining free of clinical and immunological evidence of Newcastle disease as demonstrated by negative hemagglutination inhibition tests conducted on samples drawn at 10-day intervals throughout the surveillance period; or

(ii) Once weekly collection of carcasses of all birds in the flock or flocks of origin, dying during the surveillance period, with laboratory examination of such carcasses including use of the embryonated egg inoculation technique,[6] to detect Newcastle disease virus; and once monthly collection of tracheal and cloacal swabs from not less than 10 percent of the birds in the flock or flocks of origin, for laboratory testing.[6] All examinations and tests shall be negative for evidence of Newcastle disease.

The laboratory conducting the examinations and testing required in this paragraph shall be a facility located in the country of origin of the eggs being certified, and shall be approved by the national government of said country for this purpose in accordance with criteria acceptable to the Deputy Administrator, Veterinary Services.[7]

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[4] The requirements for the importation of hatching eggs are stated in Part 92 of this chapter.

[5] A sentinel bird is a specific pathogen-free chicken which has not been infected with, exposed to, or immunized with any strain of Newcastle disease virus and is therefore susceptible to Newcastle disease. Information regarding sources of sentinel birds may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

[6] Technical information on laboratory methods and procedures may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

[7] Information regarding the identity of such approved laboratory facilities and

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(h) Eggs, other than hatching eggs, of poultry, game birds, and other birds, which do not qualify for importation under paragraphs (f) or (g) of this section may be permitted entry in specific cases by the Deputy Administrator, Veterinary Services, upon application to him, if:

(1) Such eggs are transported under U.S. Government seal to a processing establishment approved by the Deputy Administrator for breaking and pasteurization, and the Deputy Administrator determines that such handling and use of the eggs does not involve a risk of the introduction or dissemination of visceratropic velogenic Newcastle disease into the United States. Shells of such eggs, cases, and other packing materials used in the importation shall be disposed of under the supervision of a Department inspector in a manner approved by the Deputy Administrator as adequate to effectuate the purposes of this section; or

(2) Such eggs are imported for scientific, educational or research purposes and the importer has provided to the Deputy Administrator, Veterinary Services, evidence, satisfactory to the Deputy Administrator, that he has the equipment, facilities, and capability to store, handle, process, or disinfect the eggs in a manner adequate to prevent the introduction or dissemination of visceratropic velogenic Newcastle disease into the United States; or

(3) Such eggs do not qualify for importation under paragraph (h) (1) or (2) of this section and the Deputy Administrator, Veterinary Services, authorizes such importation. Permission will be given only when the Deputy Administrator determines that such importation will not constitute a risk of introduction or dissemination of visceratropic velogenic Newcastle disease into the United States.

(Approved by the Office of Management and Budget under control number 0579-0015)

[39 FR 39546, Nov. 8, 1974; 39 FR 41242, Nov. 26, 1974, as amended at 40 FR 14571, Apr. 1, 1975; 45 FR 29270, May 2, 1980; 45 FR 65520, Oct. 3, 1980; 48 FR 57472, Dec. 30, 1983; 50 FR 7328, Feb. 22, 1985; 50 FR 28560, July 15, 1985]

§ 94.7 Disposal of animals, meats, and other articles ineligible for importation.

(a) Ruminants and swine, and fresh, chilled, or frozen meats, prohibited importation under § 94.1, which come into the United States by ocean vessel and are offered for entry and refused admission into this country shall be destroyed or otherwise disposed of as the Deputy Administrator, Veterinary Services, may direct pursuant to section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), unless they are exported by the consignee within 48 hours, and meanwhile are retained under such isolation and other safeguards as the Deputy Administrator, Veterinary Services, may require to prevent the introduction or dissemination of livestock or poultry diseases into the United States.

(b) Ruminants and swine, and fresh, chilled, or frozen meats, prohibited importation under § 94.1, which come into the United States aboard an airplane or railroad car and are offered for entry and refused admission into this country shall be destroyed or otherwise disposed of as the Deputy Administrator, Veterinary Services, may direct pursuant to section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), unless they are exported by the consignee within 24 hours and meanwhile are retained under such isolation and other safeguards as the Deputy Administrator, Veterinary Services, may require to prevent the introduction or dissemination of livestock or poultry diseases into the United States.

(c) Ruminants and swine, and fresh, chilled, or frozen meats, prohibited importation under § 94.1, which come into the United States by any means other than ocean vessel, airplane, or railroad car and are offered for entry and refused admission into this country shall be destroyed or otherwise disposed of as the Deputy Administrator, Veterinary Services, may direct pursuant to section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306),

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other criteria for such approval may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

unless they are exported by the consignee within 8 hours on the same means of conveyance and meanwhile are retained under such isolation and other safeguards as the Deputy Administrator, Veterinary Services, may require to prevent the introduction or dissemination of livestock or poultry diseases into the United States.

(d) Ruminants and swine, and fresh, chilled, or frozen meats, prohibited importation under § 94.1, which come into the United States by any means but are not offered for entry into this country; and other animals, meats, and other articles prohibited importation under other sections of this part which come into the United States by any means, whether they are offered for entry into this country or not, shall be immediately destroyed or otherwise disposed of as the Deputy Administrator, Veterinary Services, may direct at any time in accordance with section 2 of the Act of February 2, 1903, as amended, or section 2 of the Act of July 2, 1962 (21 U.S.C. 111, 134a).

[38 FR 2752, Jan. 30, 1973]

§ 94.8 Pork and pork products from countries where African swine fever exists or is reasonably believed to exist.

African swine fever is potentially the most dangerous and destructive of all communicable swine diseases. The causative virus is highly virulent and may be present in pork and pork products originating in countries where the disease exists. The only known practical method of destroying the contagion of the disease in pork and pork products is by heat treatment. In view of these circumstances and in order to prevent the introduction and dissemination of the contagion of African swine fever, the regulations in this section are promulgated with respect to the importation of pork and pork products from the following countries where the disease exists or the administrator has reason to believe the disease exists because of the following factors:

"1. When a country allows the importation of host animals, pork or pork products or vectors of the disease from a country affected with African swine fever under conditions less stringent than those prescribed for importing host animals, pork or pork products or vectors of the disease into the United States from a country affected with African swine fever; or

"2. When a country allows the movement or use of African swine fever virus or cultures under conditions less stringent than those prescribed for similar movements or use into or within the United States; or

"3. The proximity of a country to another country or countries with known outbreaks of African swine fever; or

"4. A country's lack of a disease detection, control or reporting system capable of detecting or controlling the disease and reporting it to the United States in time to allow this country to take appropriate action to prevent the introduction of African swine fever into this country; or

"5. Any other fact or circumstance found to exist which constitutes a risk of introduction of the disease into the United States."

All countries of Africa.
Belgium.
Brazil.
Cuba.
Haiti.
Italy.
Malta.
Portugal.
Spain.

(a) No pork or pork product will be permitted entry into the United States from any country listed in this section unless;

(1) Such pork or pork product has been fully cooked by a commercial method in a container hermetically sealed promptly after filling but before such cooking, so that such cooking and sealing produced a fully-sterilized product which is shelf-stable without refrigeration; or

(2) Such pork or pork product is not otherwise prohibited importation under this part and is consigned directly from the port of entry in the United States to a meat processing establishment operating under Federal meat inspection, approved by the Deputy Administrator, Veterinary Services for further processing of such pork or pork product by heat.

(3) Such pork or pork product meets the conditions of paragraphs (a)(3)(i) through (a)(3)(vi) of this section;

(i) It was derived from pork or pork products:

(A) Which originated from swine raised and slaughtered in a country not listed in this section;

(B) Which were shipped from the country of origin to a processing establishment[1] in a country listed in this section in a closed container sealed with serially numbered seals applied by an official of the national government of the country of origin;

(C) Which were accompanied from the country of origin to such processing establishment by a certificate signed by an official of the national government of the country of origin specifying the country of origin, the processing establishment to which the pork was consigned, and the numbers of the seals applied; and

(D) Which were taken out of the container at such processing establishment only after an official of the national government of the country where such processing establishment is located determined that the seals were intact and free of any evidence of tampering, and had so stated on the certificate referred to in paragraph (a)(3)(i)(C) of this section;

(ii) All bones were completely removed;

(iii) It was heated by other than a flash-heating method at the processing establishment referred to in paragraph (a)(3)(i)(B) of this section, to an internal temperature of at least 69 °C. (156 °F.) throughout (this must have occurred after the bones had been removed);

(iv) The processing establishment referred to in paragraph (a)(3)(i)(B) of this section:

(A) Does not receive or process any live swine, uses only pork or pork products which originate in countries not listed in this section, and processes port or pork products only in accordance with paragraphs (a)(3)(i) through (a)(3)(vi) of this section;

(B) Is operated by persons who have entered into a valid written compliance agreement with Veterinary Services whereby such persons have agreed to maintain on file at the establishment for at least two years copies of the certificates referred to in paragraph (a)(3)(i)(C) of this section, to allow Veterinary Services personnel to make unannounced inspections as necessary to monitor compliance with the provisions of this section, and have agreed to otherwise comply with the provisions of this section;

(C) Is operated by persons who have entered into a trust fund agreement executed by such persons and Veterinary Services; pursuant to the trust fund agreement the establishment is current in paying the cost for Veterinary Services personnel to inspect the establishment (it is anticipated that such inspections will occur once per year), including travel, salary, subsistence, administrative overhead, and other incidental expenses (including excess baggage provisions up to 150 pounds); and in addition the establishment has on deposit with the Animal and Plant Health Inspection Service an unobligated amount equal to the cost for Veterinary Services personnel to conduct one inspection;

(v) It was processed in a country listed in this section only at one processing establishment; and

(vi) It is accompanied at the time of importation into the United States by a certificate issued by an official of the national government of the country wherein the processing establishment referred to in paragraph (a)(3)(i)(B) of this section is located stating that all of requirements of this section have been met.

(b) Pork or pork products consigned from the port of entry to an approved establishment under the provisions of paragraph (a)(2) of this section shall be moved from the port of entry to the approved establishment under Customs seals or seals of the Deputy Administrator, Veterinary Services and shall be otherwise handled as the Deputy Administrator, Veterinary Services may direct in order to guard against the introduction and dissemination of the contagion of African swine fever. Seals applied under this section shall not be broken except by persons authorized to do so by the Deputy Administrator, Veterinary Services.

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[1] As a condition of entry into the United States, pork or pork products must also meet all of the requirements of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and regulations thereunder (9 CFR Part 301 *et seq.*), including requirements that the pork or pork products be prepared only in approved establishments.

(c) Pork or pork products imported into the United States from a country listed in this section which do not meet the requirements specified in this section shall be seized, quarantined, and disposed of as the Deputy Administrator, Veterinary Services may direct in order to guard against the introduction and dissemination of the contagion of the disease.

(d) Any compliance agreement may be cancelled orally or in writing by the inspector who is supervising its enforcement whenever the inspector finds that such person has failed to comply with the provisions of this section or any conditions imposed pursuant to such provisions. If the cancellation is oral, the decision and the reasons therefore shall be confirmed in writing, as promptly as circumstances allow. Any person whose compliance agreement has been cancelled may appeal the decision, in writing, within ten (10) days after receiving written notification of the cancellation. The appeal shall state all of the facts and reasons upon which the person relies to show that the compliance agreement was wrongfully cancelled. The Deputy Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of Practice concerning such a hearing will be adopted by the Deputy Administrator.

[28 FR 5980, June 13, 1963]

EDITORIAL NOTE: For Federal Register citations affecting § 94.8, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 94.9 Pork and pork products from countries where hog cholera exists.

(a) Hog cholera is one of the most dangerous and destructive of all swine diseases. The causative virus is highly virulent and is likely to be present in pork and pork products originating in countries where the disease exists. The disease is known to exist in all countries of the world except Australia, Canada, Denmark, Dominican Republic, Finland, Great Britain (England, Scotland, Wales, and Isle of Man), Iceland, Northern Ireland, Norway, the Republic of Ireland, Trust Territory of the Pacific Islands, and New Zealand. The only known practical methods of destroying the contagion of the disease in pork and pork products are by a treatment as prescribed in this section. In view of these circumstances and in order to prevent the introduction and dissemination of the contagion of hog cholera, the regulations in this section are promulgated with respect to the importation of pork and pork products from all countries of the world except: Australia, Canada, Denmark, Dominican Republic, Finland, Great Britain (England, Scotland, Wales, and Isle of Man), Iceland, Northern Ireland, the Republic of Ireland, Trust Territory of the Pacific Islands, New Zealand and Sweden.[6]

(b) No pork or pork product will be permitted entry into the United States from any country where hog cholera is known to exist unless it complies with the following requirements:

(1) Such pork or pork product has been treated in accordance with one of the following procedures:

(i) Such pork and pork product has been fully cooked by a commercial method in a container hermetically sealed promptly after filling but before such cooking, so that such cooking and sealing produced a fully sterilized product which is shelf-stable without refrigeration;

(ii) Such pork or pork product is in compliance with the following requirements:

(*a*) All bones have been completely removed in the country of origin, and

(*b*) Such article has received heat treatment producing an internal temperature of 156° F.; or

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[6] See also other provisions of this part and Parts 92, 95, 96, and 327 of this chapter for other prohibitions and restrictions upon importation of swine and their products.

(iii) Such pork or pork product is in compliance with the following requirements:

(*a*) All bones have been completely removed in the country of origin, and

(*b*) The meat has been held in an unfrozen, fresh condition for at least 3 days immediately following the slaughter of the animals from which it was derived, and

(*c*) The meat has been thoroughly cured and fully dried for a period of not less than 90 days so that the product is shelf stable without refrigeration: *Provided,* That the period of curing and drying shall be 45 days if the pork or pork product is accompanied to the processing establishment by a certificate of an official of the national government of a hog cholera free country which specifies that:

(*1*) The pork involved originated in that country and the pork or pork product was consigned to a processing establishment in ——— (a country not listed in paragraph (a) of this section as free of hog cholera), in a closed container sealed by the national veterinary authorities of the hog cholera free country by seals of a serially numbered type; and

(*2*) The numbers of the seals used were entered on the meat inspection certificate of the hog cholera free country which accompanied the shipment from such free country: *And, provided further,* That the certificate required by paragraph (b)(3) of this section also states that: The container seals specified in paragraph (b)(1)(iii)(c)(*1*) of this section were found intact and free of any evidence of tampering on arrival at the processing establishment by a national veterinary inspector; and the processing establishment from which the pork or pork product is shipped to the United States does not receive or process any live swine, and uses only pork or pork product which originates in countries listed in paragraph (a) of this section as free of hog cholera and processes all such pork or pork products in accordance with paragraphs (b)(1), (i), (ii), or (iii) of this section.

(2) Articles under § 94.9(b) (1) (ii) or (iii) were prepared in an inspected establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act and the regulations in § 327.2 in Chapter III of this title; and,

(3) In addition to the certificate required by § 327.4 of this title, articles prepared under § 94.9(b)(1) (ii) or (iii) shall be accompanied by a certificate stating the facts specified in paragraphs (b)(1)(ii) or (iii) of this section, and issued by an official of the national government of the country of origin who is authorized to issue the certificates required by § 327.4 of this title.[9]

(4) Small amounts of pork or pork product, subject to the restrictions in this section, may in specific cases be imported for purposes of examination, testing, or analysis if the importer applies for and receives written approval for such importation from the Deputy Administrator, Veterinary Services. Approval will be granted only when the Deputy Administrator determines that the articles have been processed by heat in a manner so that such importation will not endanger the livestock of the United States.

(c) Thoroughly cured and fully dried pork and pork products from countries where both hog cholera and swine vesicular disease are known or considered to exist need not comply with the requirements of § 94.9(b)(1)(iii) if they are in compliance with the provisions of § 94.12(b)(1)(iii).

(Approved by the *Office of Management* and Budget under control number 0579-0015)

[37 FR 21149, Oct. 6, 1972]

EDITORIAL NOTE: For Federal Register citations affecting § 94.9, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 94.10 Swine from countries where hog cholera exists; importations prohibited.

Whereas it has been determined that hog cholera exists in all countries of the world except Australia, Canada, Denmark, Dominican Republic, Finland, Great Britain (England, Scotland, Wales, and Isle of Man), Iceland, Northern Ireland, Norway, the Republic of Ireland, Trust Territory of the

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[9] The certification required may be placed on the certificate prescribed by § 327.4 or may be contained in a separate document.

Pacific Islands, New Zealand and Sweden and that swine which originate in or are shipped from or transit any country except those listed, would, if brought into the United States, be likely to introduce or disseminate hog cholera into the United States, it is hereby further determined that, in order to protect the livestock of the United States, it is necessary to prohibit the movement of such swine into the United States and such movement is hereby prohibited except for wild swine which may be allowed importation by the Deputy Administrator upon request in specific cases under § 92.4(c) or § 92.2 of this chapter.

[37 FR 21150, Oct. 6, 1972, as amended at 37 FR 22728, Oct. 21, 1972; 37 FR 24656, Nov. 18, 1972; 38 FR 15363, June 11, 1973; 44 FR 2568, Jan. 12, 1979; 49 FR 21042, May 18, 1984; 50 FR 16695, Apr. 29, 1985]

§ 94.11 Restrictions on importation of meat and other animal products from specified countries.

(a) Bahama Islands, Channel Islands, Denmark, Finland, Great Britain (England, Scotland, Wales, and Isle of Man), Japan, Norway, and Sweden, which are declared in § 94.1 to be free of rinderpest and foot-and-mouth disease, supplement their national meat supply by the importation of fresh, chilled, or frozen meat of ruminants or swine from countries that are designated in § 94.1(a) to be infected with rinderpest or foot-and-mouth disease; or have a common land border with countries designated as infected with rinderpest or foot-and-mouth disease; or import ruminants or swine from countries designated as infected with rinderpest or foot-and-mouth disease under conditions less restrictive than would be acceptable for importation into the United States. Thus, even though this Department has declared such countries to be free of rinderpest and foot-and-mouth disease, the meat and other animal products produced in such free countries may be commingled with the fresh, chilled, or frozen meat of animals from an infected country, resulting in an undue risk of introducing rinderpest or foot-and-mouth disease into the United States. Therefore, meat of ruminants or swine, and other animal products, and ship stores, airplane meals, and baggage containing such meat or animal products originating in the free countries listed in this section shall not be imported into the United States unless the following requirements in addition to other applicable requirements of Chapter III of this title are met. However, meat and meat products which meet the requirements of § 94.4 do not have to comply with the requirements of this section. As used in this section the term "other animal product" means all parts of the carcass of any ruminant or swine, other than meat and articles regulated under Part 95 or 96 of this chapter.

(b) All meat or other animal product from such countries, whether in personal-use amounts or commercial lots (except that which has been fully cooked by a commercial method in a container hermetically sealed promptly after filling but before such cooking and sealing produced a fully sterilized product which is shelf-stable without refrigeration) shall have been prepared only in an inspected establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the regulations in § 327.2, Chapter III of this title, issued thereunder, and shall be accompanied by a Department-approved meat inspection certificate prescribed in § 327.4 in Chapter III of this title, or similar certificate approved by the Deputy Administrator, Veterinary Services, as adequate to effectuate the purposes of this section, regardless of the purpose or amount of product in the shipment.

(c) Shipments of such meat or other animal product must be accompanied by an additional certificate signed by a full-time salaried veterinary official of the agency in the National Government having responsibility for the health of animals within that country, giving the name and official establishment number of the establishment where the animals involved were slaughtered and stating that:

(1) The slaughtering establishment is not permitted to receive animals that originated in, or have ever been in, or that have been aboard a means

of conveyance at the time such means of conveyance called at or landed at a port in, a country listed in § 94.1(a) as a country infected with rinderpest or foot-and-mouth disease;

(2) The slaughtering establishment is not permitted to receive meat or other animal products derived from ruminants or swine which originated in such a rinderpest or foot-and-mouth disease infected country, or meat or other animal products from a rinderpest and foot-and-mouth disease free country transported through a rinderpest or foot-and-mouth disease infected country except in containers sealed with serially numbered seals of the National Government of the noninfected country of origin;

(3) The meat or other animal product covered by the certificate was derived from animals born and raised in a country listed in § 94.1(a)(2) as free of rinderpest and foot-and-mouth disease and the meat or other animal product has never been in any country in which rinderpest or foot-and-mouth disease existed;

(4) The meat or other animal product has been processed, stored, and transported to the means of conveyance that will bring the article to the United States in a manner to preclude its being commingled or otherwise in contact with meat or other animal products that do not comply with the conditions contained in this certificate.

(Approved by the Office of Management and Budget under control number 0579-0015)

[38 FR 2752, Jan. 30, 1973]

EDITORIAL NOTE: For Federal Register citations affecting § 94.11, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 94.12 Pork and pork products from countries where swine vesicular disease exists.

(a) Swine vesicular disease is considered to exist in all countries of the world except Australia, Bahama Islands, Bulgaria, Canada, Central American countries, Denmark, Dominican Republic, Finland, Great Britain (England, Scotland, Wales, and the Isle of Man), Greenland, Haiti, Hungary, Iceland, Luxembourg, Mexico, New Zealand, Northern Ireland, Norway, Panama, Republic of Ireland, Rumania, Sweden, Switzerland, Trust Territories of the Pacific Islands, and Yugoslavia.

(b) No pork or pork products shall be permitted entry into the United States from any country where swine vesicular disease is considered to exist unless it complies with the following requirements and it is not otherwise prohibited importation under this part:

(1) Such pork or pork product has been treated in accordance with one of the following procedures:

(i) Such pork or pork product has been fully cooked by a commercial method in a container hermetically sealed promptly after filling, but before such cooking, so that such cooking and sealing produced a fully sterilized product which is shelf-stable without refrigeration; or

(ii) Such pork or pork product is in compliance with the following requirements:

(A) All bones have been completely removed in the country of origin, and

(B) Such article has received heat treatment in a commercially accepted manner used for perishable canned pork products that produces an internal temperature of 156° F.; or

(iii) Such pork or pork product if cured and dried is in compliance with the following requirements:

(A) All bones have been completely removed in the country of origin, and

(B) Such pork or pork products shall be consigned directly from the port of entry in the United States to a meat processing establishment operating under Federal meat inspection and approved by the Deputy Administrator, Veterinary Services[10] for heating to an internal temperature of 166° F, or

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[10] Information as to the identity of approved establishments may be obtained from, and request for approval of any establishment may be made to, the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250. Establishments will be approved only if the Deputy Administrator, Veterinary Services, determines that the imported

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(iv) Such pork or pork product, if it originated in a swine vesicular disease free country, has been cured and dried and is in compliance with the following requirements:

(A) All bones have been completely removed in the country of origin, and

(B)(*1*) Such pork or pork product is accompanied from the swine vesicular disease free country of origin to the processing establishment in the swine vesicular disease infected country by a certificate signed by an official of the National Government of the swine vesicular disease free country of origin specifying that the pork or pork product involved originated in that country and the pork or pork product was consigned to a processing establishment in ——— (a country not listed in paragraph (a) of this section as free of swine vesicular disease), in a closed container sealed by the national veterinary authorities of the swine vesicular disease free country of origin by seals of a serially numbered type. The numbers of these seals shall be entered on this certificate; and

(*2*) The certificate required by paragraph (b)(3) of this section shall also state that:

(*i*) The container seals specified in paragraph (b)(1)(iv)(B)(*1*) of this section were found intact and free of any evidence of tampering on arrival at the processing establishment in the swine vesicular disease infected country by a national veterinary inspector of that country,

(*ii*) The processing establishment from which the pork or pork product was shipped to the United States does not receive or process any live swine, and uses only pork or pork products which originate in countries listed in paragraph (a) of this section as free of swine vesicular disease; and

(*iii*) That such establishment processes all such pork or pork products in accordance with paragraph (b)(1) (i), (ii), (iii) or (iv) of this section.

(2) Articles under paragraph (b)(1) (ii), (iii) or (iv) of this section were prepared in an inspected establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act and the regulations in § 327.2 in Chapter III of this title; and

(3) In addition to the certificate required in § 327.4 of this title, articles prepared under paragraph (b)(1) (ii), (iii) or (iv) of this section shall be accompanied by a certificate stating the facts specified in paragraphs (b)(1) (ii), (iii)(A), or (iv)(B)(*2*) of this section. The certificate shall be issued by an official of the national government of the country of origin who is authorized to issue the certificates required by § 327.4 of this title.[9]

(4) Small amounts of pork or pork product subject to the restrictions of this section, may in specific cases be imported for purposes of examination, testing, or analysis, if the importer applies for and receives written approval for such importation from the Deputy Administrator, Veterinary Services, authorizing such importation. Approval will be granted only when the Deputy Administrator determines that the articles have been processed by heat in a manner so that such importation will not endanger the livestock of the United States.

(Approved by the Office of Management and Budget under control number 0579-0015)

[38 FR 20610, Aug. 2, 1973, as amended at 38 FR 24892, Sept. 11, 1973; 38 FR 31416, Nov. 14, 1973; 38 FR 35231, Dec. 26, 1973; 39 FR 2568, Jan. 23, 1974; 39 FR 13070; Apr. 11, 1974; 39 FR 17430, May 16, 1974; 41 FR 7109, Feb. 17, 1976; 41 FR 15001, Apr. 9, 1976; 41 FR 23699, June 11, 1976; 44 FR 26059, May 4, 1979; 48 FR 57472, Dec. 30, 1983; 50 FR 7329, Feb. 22, 1985; 50 FR 24613, June 12, 1985]

§ 94.13 Restrictions on importation of pork or pork products from specified countries.

Bahama Islands, Bulgaria, Great Britain (England, Scotland, Wales, and the Isle of Man), Hungary, Luxem-

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articles will be so handled at the establishments as to prevent the introduction and dissemination of livestock or poultry diseases into the United States. Approval of any establishment may be refused or withdrawn only after the operator thereof has been given notice of the proposed action and has had an opportunity to present his views thereon.

[9] See footnote 9 to § 94.9.

bourg, Switzerland, and Yugoslavia which are declared to be free of swine vesicular disease in § 94.12(a); are countries which either supplement their national pork supply by the importation of fresh, chilled, or frozen pork from countries where swine vesicular disease is considered to exist; or which vesicular disease is considered to exist; or which have a common border with such countries; or which have certain trade practices that are less restrictive than are acceptable to the United States. Thus, the pork or pork products produced in such countries may be commingled with fresh, chilled, or frozen meat of animals from a country where swine vesicular disease is considered to exist resulting in an undue risk of swine vesicular disease introduction into the United States. Therefore, pork or pork products and shipstores, airplane meals, and baggage containing such pork, other than those articles regulated under Part 95 or Part 96 of this chapter, produced in such countries shall not be brought into the United States unless the following requirements are met in addition to other applicable requirements of Part 327, Subchapter A, Chapter III of this title:

(a) All such pork products, except those in compliance with applicable provisions of § 94.12(b)(1)(i), shall have been prepared only in inspected establishments that are eligible to have their products imported into the United States under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the regulations in § 327.2, Chapter III of this title which are issued thereunder, and shall be accompanied by a Department-approved meat inspection certificate prescribed in § 327.4 in Chapter III of this title.

(b) Shipments of such pork or other pork products consigned to the United States, unless they are in compliance with applicable provisions of § 94.12(b), must be accompanied by an additional certificate signed by a full-time salaried veterinary official of the agency in the National Government having responsibility for the health of animals within that country, stating the name and official establishment number of the establishment where the swine involved were slaughtered and the pork was processed and also stating that:

(1) The slaughtering establishment is not permitted to receive animals that originated in, or have ever been in a country listed in § 94.12(a) as a country in which swine vesicular disease is considered to exist;

(2) The slaughtering establishment is not permitted to receive pork derived from swine which originated in such a country or pork from swine from a swine vesicular disease free country which has been transported through a country where swine vesicular disease is considered to exist except pork which was transported in containers sealed with serially numbered seals of the National Government of a country of origin listed in § 94.12 as a country considered free of the disease.

(3) The pork has been processed, stored, and transported to the means of conveyance that will bring the article to the United States in a manner that precludes its being commingled or otherwise coming in contact with pork or pork products that have not been handled in accordance with the requirements of this § 94.13.

(Approved by the Office of Management and Budget under control number 0579-0015)

[38 FR 20611, Aug. 2, 1973, as amended at 38 FR 25669, Sept. 14, 1973; 38 FR 31416, Nov. 14, 1973; 38 FR 35231, Dec. 26, 1973; 39 FR 2598, Jan. 23, 1974; 41 FR 7109, Feb. 17, 1976; 41 FR 15001, Apr. 9, 1976; 41 FR 23699, June 11, 1976; 44 FR 26059, May 4, 1979; 48 FR 57472, Dec. 30, 1983; 50 FR 7330, Feb. 22, 1985; 50 FR 24613, June 12, 1985]

§ 94.14 Swine from countries where swine vesicular disease exists; importations prohibited.

Whereas it is considered that swine vesicular disease exists in all countries of the world except those listed in § 94.12(a), and that swine which originate in or are shipped from or transit any country except those listed, would, if brought into the United States, be likely to introduce or disseminate swine vesicular disease into the United States, it is hereby further determined that, in order to protect the livestock of the United States, it is necessary to prohibit the movement of such swine into the United States and such movement is hereby prohibited: *Provided*, That wild swine may be brought into the United States in accordance with the provisions of § 92.2 or § 92.4(c) of this chapter upon request to the Deputy Administrator, Veterinary Services, in specific cases.

[38 FR 20611, Aug. 2, 1973]

§ 94.15 Animal products and materials; movement and handling.

Any animal product or material which would be eligible for entry into the United States, as specified in the regulations in this part, may transit through the United States for immediate export if the following conditions are met:

(a) Notification of the transiting of such animal product or material must be made by the importer to the Plant Protection and Quarantine Officer at the United States port of arrival prior to such transiting, and

(b) The animal product or material transited shall be contained in a sealed, leakproof carrier or container which shall remain sealed while aboard the transporting carrier or other means of conveyance, or if the container or carrier in which such animal product or material is transported is offloaded in the United States for reshipment, it shall remain sealed at all times.

[43 FR 4595, Feb. 3, 1978]

§ 94.16 Milk and milk products.

(a) The following milk products are exempt from the provisions of this part:

(1) Cheese, but not including cheese with liquid and not including cheese containing any item that is regulated by other sections of this part, unless such item is independently eligible for importation into the United States under this part;

(2) Butter; and

(3) Butteroil.

(b) Milk and milk products originating in, or shipped from, any country designated in § 94.1(a) as a country infected with rinderpest or foot-and-mouth disease may be imported into the United States if they meet the requirements of paragraphs (b) (1), (2), or (3) of this section:

(1) They are in a concentrated liquid form and have been processed by heat by a commercial method in a container hermetically sealed promptly after filling but before such heating, so as to be shelf stable without refrigeration.

(2) They are dry milk or dry milk products, including dry whole milk, nonfat dry milk, dried whey, dried buttermilk, and formulations which contain any such dry milk products, and are consigned directly to an approved establishment[11] for further processing for human food in a manner approved by the Deputy Administrator, Veterinary Services as adequate to prevent the introduction or dissemination of livestock diseases into the United States. However, in specific cases, upon request by the importer to the Deputy Administrator, Veterinary Services, and approval by the Deputy Administrator, they may be stored for a temporary period in an approved warehouse[11] under the supervision of

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[11] Information as to the identity of approved establishments, warehouses or manner of processing may be obtained from, and request for approval of any such establishment, warehouse or manner of processing may be made to the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Hyattsville, Maryland 20782. Any establishment or warehouse will be approved for the purpose of this section only if the operator has provided the Deputy Administrator, Veterinary Services, with satisfactory evidence that the establishment or warehouse has the equipment, facilities, and capability to store, handle and process the imported dry milk or dry milk product subject to § 94.16(b)(2) in a manner which will prevent the introduction or dissemination of lifestock diseases into the United States. Similarly, processing methods will be approved only if the Deputy Administrator determines they are adequate to prevent the introduction or dissemination of such diseases into the United States. Approval of any establishment or warehouse or processing method may be refused or withdrawn by the Deputy Administrator only after the operator thereof has been given notice of the proposed action and has had an opportunity to present his views thereon, and upon a determination by the Deputy Administrator

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an inspector of the Animal and Plant Health Inspection Service pending movement to an approved establishment. Such products shall be transported from the United States port of first arrival to an approved establishment[11] or an approved warehouse,[11] and from an approved warehouse[11] to an approved establishment[11] only under Department seals or seals of the U.S. Customs Service. Such seals shall be broken only by such an inspector or other person authorized to do so by the Deputy Administrator, Veterinary Services. Such products shall not be removed from the approved warehouse[11] or approved establishment[11] except upon special permission by the Deputy Administrator, Veterinary Services, and upon compliance with all the conditions and requirements specified by him for such movement in each specific case.

(3) Milk and milk products not exempted under paragraph (a) and not of classes included within the provisions of paragraphs (b) (1) or (2) of this section may be imported if the importer first applies to and receives written permission from the Deputy Administrator, Veterinary Services, authorizing such importation. Permission will be granted only when the Deputy Administrator determines that such action will not endanger the health of the livestock of the United States. Products subject to this provision include but are not limited to condensed milk, long-life milks such as sterilized milk, casein and caseinates, lactose, and lactalbumin.

(4) Small amounts of milk and milk products subject to the restrictions of this Part may in specific cases be imported for purposes of examination, testing, or analysis, if the importer applies to and receives written approval for such importation from the Deputy Administrator, Veterinary Services. Approval will be granted only when the Deputy Administrator determines that such action will not endanger the health of the livestock of the United States.

(c) Milk and milk products originating in and shipped from countries listed in § 94.1(a)(2) as free of rinderpest and foot-and-mouth disease but which have entered a port or otherwise transited any country designated in § 94.1(a)(1) as a country infected with rinderpest or foot-and-mouth disease shall not be imported into the United States unless:

(1) The product was transported under serially numbered official seals applied at the point of origin of the shipment by an authorized representative of the country of such origin.

(2) The numbers of such seals are listed on, or are on a list attached to, the bill of lading or similar document accompanying the shipment.

(3) Upon arrival of the carrier at the United States port, an inspector of the Animal and Plant Health Inspection Service determines that the seals are intact and that their numbers are in agreement with the numbers appearing on the accompanying document.

(Approved by the Office of Management and Budget under control number 0579-0015)

[40 FR 44123, Sept. 25, 1975, as amended at 48 FR 57472, Dec. 30, 1983; 50 FR 20390, May 16, 1985; 50 FR 24187, June 10, 1985]

PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

Sec.
95.1 Definitions.
95.2 Country of origin.
95.3 Byproducts from diseased animals prohibited.
95.4 [Reserved]
95.5 Untanned hides and skins; requirements for unrestricted entry.
95.6 Untanned hides and skins; importations permitted subject to restrictions.
95.7 Wool, hair, and bristles; requirements for unrestricted entry.
95.8 Wool, hair, and bristles; importations permitted subject to restrictions.
95.9 Glue stock; requirements for unrestricted entry.

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that the conditions for approval are not met. Approval of an establishment or warehouse may also be withdrawn after such notice and opportunity if the Deputy Administrator determines that such imported dry milk or milk products have been stored, handled, or processed by the operator thereof other than at an approved establishment or warehouse or other than in an approved manner.

Sec.
95.10 Glue stock; importations permitted subject to restrictions.
95.11 Bones, horns, and hoofs for trophies or museums.
95.12 Bones, horns, and hoofs; importations permitted subject to restrictions.
95.13 Bone meal for use as fertilizer or as feed for domestic animals; requirements for entry.
95.14 Blood meal, tankage, meat meal, and similar products, for use as fertilizer or animal feed; requirements for entry.
95.15 Blood meal, blood albumin, intestines, and other animal byproducts for industrial use; requirements for unrestricted entry.
95.16 Blood meal, blood albumin, intestines, and other animal byproducts for industrial use; importations permitted subject to restrictions.
95.17 Glands, organs, ox gall, and like materials; requirements for unrestricted entry.
95.18 Glands, organs, ox gall, and like materials; importations permitted subject to restrictions.
95.19 Animal stomachs.
95.20 Animal manure.
95.21 Hay and straw; requirements for unrestricted entry.
95.22 Hay and straw; importations permitted subject to restrictions.
95.23 Previously used meat covers; importations permitted subject to restrictions.
95.24 Methods for disinfection of hides, skins, and other materials.
95.25 Transportation of restricted import products; placarding cars and marking billing; unloading enroute.
95.26 Railroad cars, trucks, boats, aircraft and other means of conveyance, equipment or containers, yards, and premises; cleaning and disinfection.
95.27 Regulations applicable to products from Territorial possessions.
95.28 Hay or straw and similar material from tick-infested areas.

AUTHORITY: Sec. 2, 32 Stat. 792, as amended; 21 U.S.C. 111.

SOURCE: 28 FR 5981, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

§ 95.1 Definitions.

Whenever in the regulations in this part the following words, names, or terms are used they shall be construed, respectively, to mean:

(a) "Department" means the United States Department of Agriculture.

(b) "Veterinary Services" means the Veterinary Services unit of the Animal and Plant Health Inspection Service, United States Department of Agriculture.

(c) "Deputy Administrator" of Veterinary Services means the Deputy Administrator of Veterinary Services.

(d) "Inspector" means an inspector of Veterinary Services.

(e) [Reserved]

(f) "Approved establishment" means an establishment approved by Veterinary Services for the receipt and handling of restricted import animal byproducts.

(g) "Approved warehouse" means a warehouse having facilities approved by Veterinary Services for the handling and storage, apart from other merchandise, of restricted import products.

(h) "Approved chlorinating equipment" means equipment approved by Veterinary Services as efficient for the disinfection of effluents against the contagions of foot-and-mouth disease and rinderpest.

(i) "Approved sewerage system" means a drainage system equipped and operated so as to carry and dispose of sewage without endangering livestock through the contamination of streams or fields and approved by the Veterinary Services.

(j) "Animal byproducts" means hides, skins, hair, wool, glue stock, bones, hoofs, horns, bone meal, hoof meal, horn meal, blood meal, meat meal, tankage, glands, organs, or other parts or products of ruminants and swine unsuitable for human consumption.

(k) "Glue stock" means fleshings, hide cuttings and parings, tendons, or other collagenous parts of animal carcasses.

(l) "Bone meal" means ground animal bones and hoof meal and horn meal.

(m) "Blood meal" means dried blood of animals.

(n) "Meat meal or tankage" means the rendered and dried carcasses or parts of the carcasses of animals.

(o) "Hay and straw" means dried grasses, clovers, legumes, and similar materials or stalks or stems of various grains, such as barley, oats, rice, rye, and wheat.

§ 95.2 Country of origin.

No products or materials specified in the regulations in this part shall be imported unless there be shown upon the commercial invoice, or in some other manner satisfactory to the Deputy Administrator, Veterinary Services, the name of the country of origin of such product or material: *Provided*, That the country of origin shall be construed to mean (a) in the case of an animal byproduct, the country in which such product was taken from an animal or animals, and (b) in the case of other materials, the country in which such materials were produced.

§ 95.3 Byproducts from diseased animals prohibited.

The importation of any animal byproduct taken or removed from an animal affected with anthrax, foot-and-mouth disease, or rinderpest is prohibited.

§ 95.4 [Reserved]

§ 95.5 Untanned hides and skins; requirements for unrestricted entry.

Untanned hides and/or skins of cattle, buffalo, sheep, goats, other ruminants, and swine which do not meet the conditions of requirements specified in any one of paragraphs (a) to (e) of this section shall not be imported except subject to handling and treatment in accordance with § 95.6 after arrival at the port of entry:

(a) Hides or skins originating in and shipped directly from a country not declared by the Secretary of Agriculture to be infected with foot-and-mouth disease or rinderpest may be imported without further restriction.

(b) Hides or skins may be imported without other restriction if found upon inspection by an inspector, or by certificate of the shipper or importer satisfactory to said inspector, to be hard dried hides or skins.

(c) Abattoir hides or skins taken from animals slaughtered under national government inspection in a country[1] and in an abattoir in which is maintained an inspection service determined by the Secretary of Agriculture to be adequate to assure that they have been removed from animals found at time of slaughter to be free from anthrax, foot-and-mouth disease, and rinderpest, and to assure further the identity of such materials until loaded upon the transporting vessel, may be imported without other restriction if accompanied by a certificate bearing the seal of the proper department of such national government and signed by an official veterinary inspector of such country showing that the therein described hides or skins were taken from animals slaughtered in such specified abattoir and found free from anthrax, foot-and-mouth disease, and rinderpest.

(d) Hides or skins may be imported without other restriction if shown upon inspection by an inspector, or by certificate of the shipper or importer satisfactory to said inspector, to have been pickled in a solution of salt containing mineral acid and packed in barrels, casks, or tight cases while still wet with such solution.

(e) Hides or skins may be imported without other restriction if shown upon inspection by an inspector, or by certificate of the shipper or importer satisfactory to said inspector, to have been treated with lime in such manner and for such period as to have become dehaired and to have reached the stage of preparation for immediate manufacture into products ordinarily made from rawhide.

(Approved by the Office of Management and Budget under control number 0579-0015)

[28 FR 5981, June 13, 1963, as amended at 48 FR 57472, Dec. 30, 1983]

§ 95.6 Untanned hides and skins; importations permitted subject to restrictions.

Hides or skins offered for importation which do not meet the conditions or requirements of § 95.5 shall be handled and treated in the following manner after arrival at the port of entry:

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[1] Names of countries of this character will be furnished upon request to Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, Hyattsville, Maryland 20782.

(a) They shall be consigned from the coast or border port of arrival to an approved establishment and shall be subject to disinfection by such method or methods as the Deputy Administrator, Veterinary Services may prescribe unless the said establishment discharges drainage into an approved sewerage system or has an approved chlorinating equipment adequate for the proper disinfection of effluents: *Provided, however,* That upon permission of the Deputy Administrator, Veterinary Services such hides or skins may be stored for a temporary period in approved warehouses under bond, and under the supervision of an inspector: *And provided further,* That I. T. or inbound shipments of hides or skins may go forward under customs seals from a coast or border port of arrival, with the approval of an inspector at said port, to another port in the United States for consumption entry subject to the other provisions of this section.

(b) They shall be moved from the coast or border port of arrival or, in case of I. T. or in-bound shipments, from the interior port to the approved establishment in cars or trucks or in vessel compartments with no other materials contained therein, sealed with seals of the Department, which shall not be broken except by inspectors or other persons authorized by the Deputy Administrator, Veterinary Services so to do, or without sealing as aforesaid and with other freight when packed in tight cases or casks acceptable to the inspector in charge at the port of entry.

(c) They shall be handled at the approved establishment under the direction of an inspector in a manner approved by the Deputy Administrator, Veterinary Services to guard against the dissemination of foot-and-mouth disease and rinderpest. They shall not be removed therefrom except upon special permission of the Deputy Administrator, Veterinary Services and upon compliance with all the conditions and requirements of this section relative to the movement of the said hides and skins from the port of arrival to the said establishment.

§ 95.7 Wool, hair, and bristles; requirements for unrestricted entry.

Wool, hair, or bristles derived from ruminants and/or swine which do not meet the conditions or requirements specified in any one of paragraphs (a) to (d) of this section shall not be imported except subject to handling and treatment in accordance with § 95.8 after their arrival at the port of entry: *Provided, however,* That no blood-stained wool, hair, or bristles shall be imported under any condition:

(a) Such wool, hair, or bristles may be imported without other restriction if originating in and shipped directly from a country not declared by the Secretary of Agriculture to be infected with foot-and-mouth disease or rinderpest.

(b) Wool or hair clipped from live animals or pulled wool or hair may be imported without other restriction if the said wool or hair is reasonably free from animal manure in the form of dung locks or otherwise.

(c) Wool, hair, or bristles taken from sheep, goats, cattle, or swine, when such animals have been slaughtered under national government inspection in a country[1] and in an abattoir in which is maintained an inspection service determined by the Secretary of Agriculture to be adequate to assure that such materials have been removed from animals found at time of slaughter to be free from anthrax, foot-and-mouth disease, and rinderpest, and to assure further the identity of such materials until loaded upon the transporting vessel, may be imported without other restriction if accompanied by a certificate bearing the seal of the proper department of said national government and signed by an official veterinary inspector of such country showing that the therein described wool, hair, or bristles were taken from animals slaughtered in such specified abattoir and found free from anthrax, foot-and-mouth disease, and rinderpest.

(d) Wool, hair, or bristles which have been scoured, thoroughly washed, or dyed may be imported without other restriction.

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[1] See footnote 1 to § 95.5.

(Approved by the Office of Management and Budget under control number 0579-0015)

[28 FR 5981, June 13, 1963, as amended at 48 FR 57472, Dec. 30, 1983]

§ 95.8 Wool, hair, and bristles; importations permitted subject to restrictions.

Wool, hair, or bristles offered for importation which do not meet the conditions or requirements of § 95.7 shall be handled and treated in the following manner after arrival at the port of entry:

(a) Such wool, hair, or bristles shall be consigned from the coast or border port of arrival to an approved establishment: *Provided, however,* That upon permission by the Deputy Administrator, Veterinary Services such wool, hair, or bristles may be stored for a temporary period in approved warehouses under bond and under the supervision of an inspector: *And provided further,* That I. T. on in-bond shipments of wool, hair, or bristles may go forward under customs seals from a coast or border port of arrival, with the approval of an inspector at said port, to another port for consumption entry, subject to the other provisions of this section.

(b) Such wool, hair, or bristles shall be moved from the coast or border port of arrival or, in the case of I. T. or in-bond shipments, from the interior port to the establishment in cars or trucks or in vessel compartments with no other materials contained therein, sealed with seals of the Department, which shall not be broken except by inspectors or other persons authorized by the Deputy Administrator, Veterinary Services so to do, or without sealing as aforesaid and with other freight when packed in tight cases acceptable to an inspector.

(c) Such wool, hair, or bristles shall be handled at the establishment under the direction of an inspector in a manner approved by the Deputy Administrator, Veterinary Services to guard against the dissemination of foot-and-mouth disease and rinderpest. Such products shall not be removed therefrom except upon special permission of the Deputy Administrator, Veterinary Services and upon compliance with all the conditions and requirements of this section relative to the movement of the said wool, hair, or bristles from the port of arrival to the said establishment.

§ 95.9 Glue stock; requirements for unrestricted entry.

Glue stock which does not meet the conditions or requirements specified in any one of paragraphs (a) to (c) of this section shall not be imported except subject to handling and treatment in accordance with § 95.10 after arrival at the port of entry:

(a) Glue stock originating in and shipped directly from a country not declared by the Secretary of Agriculture to be infected with foot-and-mouth disease or rinderpest may be imported without other restriction.

(b) Glue stock may be imported without other restriction if found upon inspection by an inspector, or by certificate of the shipper or importer satisfactory to said inspector, to have been properly treated by acidulation or by soaking in milk of lime or a lime paste; or to have been dried so as to render each piece of the hardness of a sun-dried hide.

(c) Glue stock taken from cattle, sheep, goats, or swine slaughtered under national government inspection in a country[1] and in an abattoir in which is maintained an inspection service determined by the Secretary of Agriculture to be adequate to assure that such materials have been removed from animals found at time of slaughter to be free from anthrax, foot-and-mouth disease, and rinderpest, and to assure further the identity of such materials until loaded upon the transporting vessel, may be imported without other restriction if accompanied by a certificate bearing the seal of the proper department of said national government and signed by an official veterinary inspector of such country showing that the therein described glue stock was taken from animals slaughtered in such specified abattoir and found free from anthrax foot-and-mouth disease, and rinderpest.

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[1] See footnote 1 to § 95.5.

(Approved by the Office of Management and Budget under control number 0579-0015)

[28 FR 5981, June 13, 1963, as amended at 48 FR 57472, Dec. 30, 1983]

§ 95.10 Glue stock; importations permitted subject to restrictions.

Glue stock offered for importation which does not meet the conditions or requirements of § 95.9 shall be handled and treated in the following manner after arrival at the port of entry:

(a) It shall be consigned from the coast or border port of arrival to an approved establishment and shall be subject to disinfection by such method or methods as the Deputy Administrator, Veterinary Services may prescribe unless the said establishment discharges drainage into an approved sewerage system or has an approved chlorinating equipment adequate for the proper disinfection of effluents: *Provided, however,* That upon permission by the Deputy Administrator, Veterinary Services glue stock may be stored for a temporary period in approved warehouses under bond and under the supervision of an inspector: *And provided further,* That I. T. or in-bond shipments of glue stock may go forward under customs seals from a coast or border port of arrival with the approval of an inspector at said port to another port for consumption entry, subject, after arrival at the latter port, to the other provisions of this section.

(b) It shall be moved from the coast or border port of arrival or, in case of I. T. or in-bond shipments, from the interior port to the establishment in cars or trucks or in vessel compartments with no other materials contained therein, sealed with seals of the Department, which shall not be broken except by inspectors or other persons authorized by the Deputy Administrator, Veterinary Services so to do, or without sealing as aforesaid and with other freight when packed in tight cases or casks acceptable to an inspector at port of entry.

(c) It shall be handled at the establishment under the direction of an inspector in a manner approved by the Deputy Administrator, Veterinary Services to guard against the dissemination of foot-and-mouth disease and rinderpest. It shall not be removed therefrom except upon special permission of the Deputy Administrator, Veterinary Services and upon compliance with all the conditions and requirements of this section relative to the movement of the said glue stock from the port of arrival to the said establishment.

§ 95.11 Bones, horns, and hoofs for trophies or museums.

Clean, dry bones, horns, and hoofs, that are free from undried pieces of hide, flesh, and sinew and are offered for entry as trophies or for consignment to museums may be imported without other restrictions.

§ 95.12 Bones, horns, and hoofs; importations permitted subject to restrictions.

Bones, horns, and hoofs offered for importation which do not meet the conditions or requirements of § 95.11 shall be handled and treated in the following manner after arrival at the port of entry:

(a) They shall be consigned from the coast or border port of arrival to an approved establishment having facilities for their disinfection or their conversion into products customarily made from bones, horns, or hoofs: *Provided, however,* That I. T. or in-bond shipments of bones, horns, or hoofs may go forward under customs seals from a coast or border port of arrival, with the approval of an inspector at said port, to another port for consumption entry subject to the other provisions of this section.

(b) They shall be moved from the coast or border port of arrival or, in case of I. T. or in-bond shipments, from the interior port to the establishment in cars or trucks with no other materials contained therein, sealed with seals of the Department, which shall not be broken except by inspectors or other persons authorized by the Deputy Administrator, Veterinary Services so to do, or without sealing as aforesaid and with other freight when packed in tight cases or casks acceptable to an inspector at the port of entry.

(c) They shall be handled at the establishment under the direction of an inspector in a manner to guard against the dissemination of anthrax, foot-and-mouth disease, and rinderpest, and the bags, burlap, or other containers thereof, before leaving the establishment, shall be disinfected by heat or otherwise, as directed by the Deputy Administrator, Veterinary Services or burned at the establishment. They shall not be removed therefrom except upon special permission of the Deputy Administrator, Veterinary Services and upon compliance with all the conditions and requirements of this section relative to the movement of the said bones, horns, and hoofs.

§ 95.13 Bone meal for use as fertilizer or as feed for domestic animals; requirements for entry.

Steamed or degelatinized or special steamed bone meal, which, in the normal process of manufacture, has been prepared by heating bone under a minimum of 20 pounds steam pressure for at least one hour at a temperature of not less than 250° Fahrenheit (121° Centigrade), may be imported without further restrictions for use as fertilizer or as feed for domestic animals if such products are free from pieces of bone, hide, flesh, and sinew and contain no more than traces of hair and wool. Bone meal for use as fertilizer or as feed for domestic animals which does not meet these requirements will not be eligible for entry.

§ 95.14 Blood meal, tankage, meat meal, and similar products, for use as fertilizer or animal feed; requirements for entry.

Dried blood or blood meal, lungs or other organs, tankage, meat meal, wool waste, wool manure, and similar products, for use as fertilizer or as feed for domestic animals, shall not be imported except subject to handling and treatment in accordance with paragraphs (a), (b), and (c) of § 95.16, unless:

(a) Such products originated in and were shipped directly from a country not declared by the Secretary of Agriculture to be infected with foot-and-mouth disease or rinderpest; or

(b) The inspector at the port of entry finds that such products have been fully processed by tanking under live steam or by dry rendering.

§ 95.15 Blood meal, blood albumin, intestines, and other animal byproducts for industrial use; requirements for unrestricted entry.

Blood meal, blood albumin, bone meal, intestines, or other animal materials intended for use in the industrial arts shall not be imported except subject to handling and treatment in accordance with § 95.16, unless such products originated in and were shipped directly from a country not declared by the Secretary of Agriculture to be infected with foot-and-mouth disease or rinderpest.

§ 95.16 Blood meal, blood albumin, intestines, and other animal byproducts for industrial use; importations permitted subject to restrictions.

Blood meal, blood albumin, bone meal, intestines, or other animal materials intended for use in the industrial arts, which do not meet the conditions or requirements of § 95.15 shall be handled and treated in the following manner after arrival at the port of entry.

(a) They shall be consigned from the coast or border port of arrival to an approved establishment: *Provided, however,* That upon permission by the Deputy Administrator, Veterinary Services they may be stored for a temporary period in approved warehouses under bond and under the supervision of an inspector: *And provided further,* That I. T. or in-bond shipments of such products may go forward under customs seals from a coast or border port of arrival, with the approval of an inspector at said port, to another port of consumption entry, subject after arrival at the latter port to the other provisions of this section.

(b) They shall be moved from the coast or border port of arrival or, in the case of I. T. or in-bond shipments, from the interior port to the establishment in cars or trucks or in vessel compartments with no other materials contained therein, sealed with seals of the Department, which shall not be broken except by Veterinary Services inspectors or other persons authorized by the Deputy Administrator, Veterinary Services so to do, or without sealing as aforesaid and with other freight when packed in tight cases or casks acceptable to an inspector at the port of entry.

(c) They shall be handled at the establishment under the direction of an inspector in a manner to guard against the dissemination of foot-and-mouth disease and rinderpest. They shall not be removed therefrom except upon special permission of the Deputy Administrator, Veterinary Services and upon compliance with all the conditions and requirements of this section relative to the movement of the said products from the port of arrival to the said establishment.

§ 95.17 Glands, organs, ox gall, and like materials; requirements for unrestricted entry.

Glands, organs, ox gall or bile, bone marrow, and various like materials derived from domestic ruminants or swine, intended for use in the manufacture of pharmaceutical products shall not be imported except subject to handling and treatment in accordance with § 95.18, unless such glands, organs, or materials originated in and were shipped directly from a country not declared by the Secretary of Agriculture to be infected with foot-and-mouth disease or rinderpest.

§ 95.18 Glands, organs, ox gall, and like materials; importations permitted subject to restrictions.

Glands, organs, ox gall or bile, bone marrow, and various like materials derived from domestic ruminants or swine, which do not meet the requirements of § 95.17 may be imported for pharmaceutical purposes if in tight containers and consigned to an approved establishment: *Provided, however*, That upon special permission of the Deputy Administrator, Veterinary Services they may be stored for a temporary period in approved warehouses under bond and under the supervision of an inspector. They shall be handled and processed at the said establishment in a manner approved by the Deputy Administrator, Veterinary Services and the containers shall be destroyed or disinfected as prescribed by him. They shall not be removed therefrom except upon special permission of the Deputy Administrator, Veterinary Services and upon compliance with all the conditions and requirements of this section relative to the movement of the said glands, organs, ox gall, and like materials from the port of arrival to the said establishment.

§ 95.19 Animal stomachs.

Stomachs or portions of the stomachs of ruminants or swine, other than those imported for food purposes under the meat-inspection regulations of the Department, shall not be imported without permission from the Deputy Administrator, Veterinary Services. Importations permitted shall be subject to such restrictions as the Deputy Administrator, Veterinary Services may deem necessary in each instance.

§ 95.20 Animal manure.

Manure of horses, cattle, sheep, other ruminants, and swine shall not be imported except upon permission from the Deputy Administrator, Veterinary Services. Importations permitted shall be subject to such restrictions as he may deem necessary in each instance: *Provided, however*, That manure produced by animals while in transit to the United States shall be subject only to the requirements of the Department regulations governing the importation of domestic livestock and other animals.

§ 95.21 Hay and straw; requirements for unrestricted entry.

Except as provided in § 95.23, hay or straw shall not be imported except subject to handling and treatment in accordance with § 95.22 after arrival at the port of entry, unless such hay or straw originated in and was shipped directly from a country not declared by the Secretary of Agriculture to be infected with foot-and-mouth disease or rinderpest.

§ 95.22 Hay and straw; importations permitted subject to restrictions.

Except as provided in § 95.28, hay or straw which does not meet the conditions or requirements of § 95.21 shall be handled and treated in the following manner upon arrival at the port of entry:

(a) Hay or straw packing materials shall be burned or disinfected at the expense of the importer or consignee in the manner and at the time directed by the Deputy Administrator, Veterinary Services.

(b) Hay or straw for use as feeding material, bedding, or similar purposes shall be stored and held in quarantine for a period of not less than 90 days in an approved warehouse at the port of entry and shall be otherwise handled as directed by the Deputy Administrator, Veterinary Services.

§ 95.23 Previously used meat covers; importations permitted subject to restrictions.

Cloth or burlap which has been used to cover fresh or frozen meats originating in any country designated in § 94.1 of this subchapter as a country in which rinderpest or foot-and-mouth disease exists, shall not be imported except under the following conditions:

(a) The cloth or burlap shall be consigned from the coast or border port of arrival to an establishment specifically approved for the purpose by the Deputy Administrator, Veterinary Services.

(b) The cloth or burlap shall be immediately moved from the coast or border port of arrival, or in case of I. T. or in-bond shipments from the interior port, to the establishment, in railroad cars or trucks, or in vessel compartments, with no other material contained therein, sealed with seals of the Department, which shall not be broken except by inspectors or other persons authorized by the Deputy Administrator, Veterinary Services: *Provided, however,* That upon permission of the Deputy Administrator, Veterinary Services, such cloth or burlap may be stored for a temporary period in approved warehouses at the port of arrival under bond and under the supervision of an inspector.

(c) The material shall be disinfected and otherwise handled at the establishment under the direction of an inspector in a manner approved by the Deputy Administrator, Veterinary Services to guard against the dissemination of foot-and-mouth disease and rinderpest, and the material shall not be removed therefrom, except upon special permission of the Deputy Administrator, Veterinary Services, until all of the conditions and requirements of this section have been complied with.

§ 95.24 Methods for disinfection of hides, skins, and other materials.

Hides, skins, and other materials required by the regulations in this part to be disinfected shall be subjected to disinfection by methods found satisfactory and approved from time to time by the Deputy Administrator, Veterinary Services.

§ 95.25 Transportation of restricted import products; placarding cars and marking billing; unloading enroute.

(a) Transportation companies or other operators of cars, trucks or other vehicles carrying import products or materials moving under restriction, other than those in tight cases or casks, shall affix to and maintain on both sides of all such vehicles durable placards not less than 5½ by 6 inches in size, on which shall be printed with permanent black ink and in boldface letters not less than 1½ inches in height the words "Restricted import product." These placards shall also bear the words "Clean and disinfect this car or truck." Each of the waybills, conductors' manifests, memoranda, and bills of lading pertaining to such shipments shall have the words "Restricted import product, clean and disinfect car or truck," plainly written or stamped upon its face. If for any reason the placards required by this section have not been affixed to each car, or the billing has not been marked by the initial or the connecting carrier, or the placards have been removed, destroyed, or rendered illegible, the placards shall be immediately affixed or replaced and the billing marked by the initial or connecting carrier, the intention being that the billing accompanying the shipment shall be marked and each car, truck or other vehicle placarded as specified in this section from the time such shipment leaves the port of entry until it is unloaded at final destination and the cars, trucks or other vehicles are cleaned and disinfected as required by § 95.26.

(b) If it is necessary to unload enroute any of the materials or products transported in a placarded car, truck or other vehicle as provided in this section, the car, truck or other vehicle from which the transfer is made and any part of the premises in or upon which the product or material may have been placed in the course of unloading or reloading shall be cleaned and disinfected by the carrier, in accordance with the provisions of § 95.26, and the said carrier shall immediately report the matter, by telegraph, to the Deputy Administrator, Veterinary Services, Washington, D.C. 20251. Such report shall include the following information: Nature of emergency; place where product or material was unloaded; original points of shipment and destination; number and materials of the original car or truck; and number and initials of the car, truck or other vehicle into which the product or material is reloaded in case the original car or truck is not used.

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[28 FR 5981, June 13, 1963, as amended at 48 FR 57472, Dec. 30, 1983]

§ 95.26 Railroad cars, trucks, boats, aircraft and other means of conveyance, equipment or containers, yards, and premises; cleaning and disinfection.

Railroad cars, trucks, boats, aircraft and other means of conveyance, equipment or containers, yards, and premises which have been used in the transportation, handling, or storing of restricted import products or materials, other than those contained in leak proof cases or casks, shall be cleaned and disinfected with a disinfectant approved for use in this part under the supervision of the division at the time and in the manner provided in this section. Except as provided in paragraph (a) of this section, such railroad cars, trucks, boats, aircraft and other means of conveyance, equipment or containers, shall not be moved in interstate or foreign commerce until they have been so treated.

(a) *Cars to be cleaned and disinfected by final carrier at destination.* Cars required by this part to be cleaned and disinfected shall be so treated by the final carrier at destination as soon as possible after unloading and before the same are moved from such final destination for any purpose: *Provided, however,* That when the products or materials are destined to points at which an inspector or other duly authorized representative of Veterinary Services is not maintained or where proper facilities cannot be provided, the transportation company shall seal, bill, and forward the cars in which the products or materials were transported to a point to be agreed upon between the transportation company and Veterinary Services, and the transportation company shall there clean and disinfect the said cars under the supervision of Veterinary Services.

(b) *Methods of cleaning and disinfecting.* (1) Railroad cars, trucks, aircraft and means of conveyance other than boats, equipment or containers, required by this part to be cleaned and disinfected shall be treated in the following manner: Collect all litter and other refuse therefrom and destroy by burning or other approved method, clean the exterior and interior of the cars or trucks, and the areas of the aircraft or other means of conveyance, equipment or containers that may have been contaminated, and saturate the entire surface with a permitted disinfectant approved for use in this part.

(2) Boats required by this part to be cleaned and disinfected shall be treated in the following manner: Collect all litter and other refuse from the decks, compartments, and all other parts of the boat used for the transportation of the products or materials covered by this part, and from the portable chutes or other appliances, fixtures or areas used in loading and unloading same, and destroy the litter and other refuse by burning or by other approved methods, and saturate the

entire surface of the said decks, compartments, and other parts of the boat with a permitted disinfectant approved for use in this part.

(3) Buildings, sheds, and premises required by this part to be disinfected shall be treated in the following manner: Collect all litter and other refuse therefrom and destroy the same by burning or other approved methods, and saturate the entire surface of the fencing, chutes, floors, walls, and other parts with a permitted disinfectant approved for use in this part.

(c) *Permitted disinfectants.* The disinfectants permitted for use in disinfecting railroad cars, trucks, boats, aircraft and other means of conveyance, equipment or containers, yards, and premises against infection of foot-and-mouth disease and rinderpest are freshly prepared solutions of:

(1) Sodium carbonate (4 percent) in the proportion of 1 pound to 3 gallons of water.

(2) Sodium carbonate (4 percent) plus sodium silicate (0.1 percent) in the proportion of 1 pound of sodium carbonate plus sodium silicate to 3 gallons of water.

(3) Sodium hydroxide (Lye) prepared in a fresh solution in the proportion of not less than 1 pound avoirdupois of sodium hydroxide of not less than 95 percent purity to 6 gallons of water, or one 13½-ounce can to 5 gallons of water.[2]

(d) *Permitted disinfectants against ticks.* The disinfectants permitted for use against tick infestation are liquefied phenol (U. S. P. strength 87 percent phenol) in the proportion of at least 6 fluid ounces to one gallon of water; or chlorinated lime (U. S. P. strength 30 percent available chlorine) in the proportion of one pound to three gallons of water; or any one of the cresylic disinfectants permitted by the Animal and Plant Health Inspection Service in the proportion of at least four fluid ounces to one gallon of water; or through application of boiling water if the treatment is against rinder-pest or foot-and-mouth disease and tick infestation; or other disinfectants or treatments approved by the Deputy Administrator, Veterinary Services.

[28 FR 5981, June 13, 1963, as amended at 32 FR 19157, Dec. 20, 1967]

§ 95.27 Regulations applicable to products from Territorial possessions.

The regulations in this part shall be applicable to all the products and materials specified in this part which are offered for entry into the United States from any place under the jurisdiction of the United States to which the animal-quarantine laws of this country do not apply.

§ 95.28 Hay or straw and similar material from tick-infested areas.

Hay or straw, grass, or similar material from tick-infested pastures, ranges, or premises may disseminate the contagion of splenetic, Southern or Texas fever when imported for animal feed or bedding; therefore, such hay or straw, grass, or similar materials shall not be imported unless such material is first disinfected with a disinfectant specified in § 95.26(d).

PART 96—RESTRICTION OF IMPORTATIONS OF FOREIGN ANIMAL CASINGS OFFERED FOR ENTRY INTO THE UNITED STATES

Sec.

96.1 Form of certificate.
96.2 Uncertified animal casings; disposition.
96.3 Instructions regarding handling certified animal casings.
96.4 Certificate; signature and title of issuing foreign official.
96.5 Certified foreign animal casings arriving at seaboard or border port.
96.6 Dried bladders, weasands, and casings.
96.7 Uncertified casings; disinfection at seaboard port.
96.8 Casings admitted on disinfection; sealing; transfer and disinfection.
96.9 Uncertified casings; transportation for disinfection; original shipping containers; disposition of salt.
96.10 Disinfecting plant and equipment for uncertified casings.

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[2] Due to the extreme caustic nature of sodium hydroxide solution, precautionary measures such as the wearing of rubber gloves, boots, raincoat and goggles should be observed. An acid solution such as vinegar shall be kept readily available in case any of the sodium hydroxide solution should come in contact with the body.

Sec.

96.11 Uncertified casings not disinfected in 30 days; disposition.
96.12 Uncertified casings; disinfection with hydrochloric acid.
96.13 Uncertified casings; disinfection with saturated brine solution.
96.14 Common carriers; marking papers.
96.15 Form for reporting release.

AUTHORITY: Sec. 2, 32 Stat. 792, as amended; 21 U.S.C. 111.

SOURCE: 28 FR 5986, June 13, 1963, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

§ 96.1 Form of certificate.

It is hereby ordered that no animal casings shall be admitted into the United States from any foreign country unless and until they are accompanied by a certificate bearing the signature of the national Government official having jurisdiction over the health of animals in the country in which the casings originated. The certificate shall be in the following form:

FOREIGN OFFICIAL CERTIFICATE FOR ANIMAL CASINGS

Place (City) ——— (Country)
——— (Date) ———

I hereby certify that the animal casings herein described were derived from healthy animals (cattle, sheep, swine, or goats), which received, ante mortem and post mortem veterinary inspections at the time of slaughter, are clean and sound, and were prepared and handled only in a sanitary manner and were not subjected to contagion prior to exportation.

Kind of casings ———
Number of packages———
Weight———
———
Identification marks on the packages ———
Consignor ———
(Address)
Consignee ———
(Destination)
Shipping marks ———
(Signature) ———
(Official issuing the certificate)
(Official title)———
(Signature) ———
(Official of the national government having jurisdiction over the health of animals in the country in which the casings originated)
(Official title) ———

(Approved by the Office of Management and Budget under control number 0579-0015)

[28 FR 5986, June 13, 1963, as amended at 48 FR 57472, Dec. 30, 1983]

§ 96.2 Uncertified animal casings; disposition.

Animal casings which are unaccompanied by the required certificate, those shipped in sheepskins or other skins as containers, and those found upon inspection to be unclean or unsound when offered for importation into the United States shall be kept in customs custody until exported or destroyed, or until disinfected and denaturated as prescribed by the Deputy Administrator, Veterinary Services in §§ 96.3–96.15.

§ 96.3 Instructions regarding handling certified animal casings.

A certificate in the English language and exact form prescribed in § 96.1 duly executed shall accompany each consignment of animal casings offered for importation into the United States.

(a) The certificate shall bear the signature of the national government official having jurisdiction over the health of animals in the country in which the casings originate. The national government official referred to in this part shall be construed to mean the official whose jurisdiction with respect to the health of animals in the foreign country is comparable to the jurisdiction of the Secretary of the United States Department of Agriculture in the United States. It should be understood that the intention is to place responsibility for issuance of the certificate upon the foreign government through its appropriate high official. The affixing of the high official's signature on the certificate may be accomplished to the satisfaction of the Department of Agriculture through printing the said official's signature in the appropriate space on the certificate at the time the certificate is printed. The other signature appearing on the certificate should be the autograph signature of the "official issuing the certificate," who may be any person authorized by the high national official to issue such certificate. The certificate shall bear the insignia of the national government of the foreign country in which the casings originate or other evidence showing that it is a national document of that country.

(b) Animal casings are not classed as meat product, therefore the certificate required for foreign meat product is not acceptable for animal casings offered for importation.

(c) Casings offered for importation into the United States shall remain in customs custody at the port until released by an inspector of Veterinary Services for admission into the United States or otherwise disposed of as required by this part.

(d) The provision that under certain conditions casings which have been offered for importation shall be exported, shall be construed to mean the removal of the casings from the United States or its possessions.

(1) The provision that under certain conditions casings be destroyed shall be construed to mean the treatment or handling of the casings in a manner to take away completely the usefulness of them as by tanking or incineration.

(2) The provision that under certain conditions casings shall be disinfected and denatured shall be construed to mean such treatment and handling as will be prescribed by the Deputy Administrator, Veterinary Services to free them from pathogenic substances or organisms, or to render such substances and organisms inert; and that the nature of the casings be changed to make them unfit for eating without destroying other useful properties. For instance, each casing may be split throughout its length and after disinfection, as above indicated, be released for industrial use.

(e) Dried intestines offered for importation into the United States for use as gut strings or similar purpose are not regarded as animal casings within the meaning of this part. Such dried intestines are classed with tendons, sinews, and similar articles and are subject to the provisions of Part 95.

§ 96.4 Certificate; signature and title of issuing foreign official.

The signature and title of the high official of the national government having jurisdiction over the health of animals in foreign countries are acceptable when printed in the appropriate space on the certificate.

§ 96.5 Certified foreign animal casings arriving at seaboard or border port.

(a) Properly certified foreign animal casings arriving in the United States at a seaboard or border port where an inspector of Veterinary Services is stationed shall be released for entry by the inspector at the seaboard or border port.

(b) Properly certified foreign animal casings arriving in the United States at a seaboard or border port where no inspector of Veterinary Services is stationed, which are destined to a point in the United States where an inspector of Veterinary Services is stationed, shall be shipped in United States Customs custody to destination for release.

(c) Properly certified foreign animal casing arriving in the United States at a seaboard or border port where no inspector of Veterinary Services is stationed, which are destined to a point in the United States where no inspector of Veterinary Services is stationed, shall be transported in United States Customs custody to the nearest point where an inspector of Veterinary Services is stationed for release at that point.

(d) Properly certified foreign animal casings forming a part of a foreign meat consignment routed through a border port to an interior point in the United States shall be transported to destination as though the entire consignment consisted of meat. In such cases the inspector of Veterinary Services who inspects the meat at destination shall supervise the release of the casings.

§ 96.6 Dried bladders, weasands, and casings.

Dried animal bladders, dried weasands, and all other dried animal casings offered for importation into the United States as food containers unaccompanied by foreign certification which have been retained in the dry state continuously for not less than 90 days from the date of shipment shown on the consular invoice, may be released for entry as food containers without disinfection.

§ 96.7 Uncertified casings; disinfection at seaboard port.

Uncertified foreign animal casings arriving at a seaboard port may be imported into the United States for use as food containers after they have been disinfected under the direct supervision of an inspector of Veterinary Services at the seaboard port.

§ 96.8 Casings admitted on disinfection; sealing; transfer and disinfection.

Foreign animal casings offered for importation into the United States which are admitted upon disinfection shall be handled as follows:

(a) The containers of such casings shall be sealed on the steamship pier or other place of first arrival. Four seals shall be affixed to both ends of each tierce, barrel, and similar container in the space where the ends of the container enter the staves, by means of red sealing wax imprinted with the No. 3 Veterinary Services brass brand from which "INSP'D & P'S'D" and the establishment number have been removed.

(b) Uncertified animal casings sealed as above indicated shall be transferred from the steamship pier or other place of first arrival to the premises of the importer or other designated place, where they shall be disinfected by the importer under the supervision of an inspector of Veterinary Services before they are offered for sale. The object of this ruling is to place full responsibility for disinfection of casings on the original importer and to prevent the sale of casings subject to disinfection by the purchaser.

§ 96.9 Uncertified casings; transportation for disinfection; original shipping containers; disposition of salt.

(a) Foreign animal casings arriving in the United States without certification may be forwarded in customs custody to Buffalo, N.Y., Chicago, Ill., Cleveland, Ohio, or South Omaha, Nebr., for disinfection under Veterinary Services supervision and release by the customs authorities in these cities, provided that before being transported over land in the United States each and every container of such casings shall be disinfected by the application of a solution of sodium hydroxide prepared as follows:

(1) Sodium hydroxide (Lye) prepared in a fresh solution in the proportion of not less than 1 pound avoirdupois of sodium hydroxide of not less than 95 percent purity to 6 gallons of water, or one 13⅓-ounce can to 5 gallons of water.[1]

(2) This solution shall be thoroughly applied to all exterior surfaces of the containers and be allowed to remain for at least thirty minutes to accomplish disinfection. The containers should then be washed with water to remove the caustic soda which otherwise might cause injury to the handlers of the packages.

(b) When uncertified foreign casings are removed from the original shipping containers these containers shall be destroyed by burning or promptly and thoroughly disinfected both inside and out with the solution and in the manner above prescribed. If these containers are to be re-used it is important that they be thoroughly washed both inside and out with water after disinfection has been completed, and in order to insure against the injurious effect of caustic soda remaining in the wood it is advisable to allow the containers to stand for not less than six hours filled with water.

(c) The salt removed from all original shipping containers of uncertified foreign animal casings shall be immediately dissolved in water and heated to boiling, or disposed of as provided in paragraph (c) (1) or (2) of this section as follows:

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[1] Due to the extreme caustic nature of sodium hydroxide solution, and of sodium carbonate solution to a lesser degree, precautionary measures such as the wearing of rubber gloves, boots, raincoat and goggles should be observed. An acid solution such as vinegar shall be kept readily available in case any of the sodium hydroxide solution should come in contact with the body.

(1) Dissolve the salt in the proportion of 90 pounds of salt to 100 gallons of water. Add 2¾ gallons of C. P. hydrochloric acid containing not less than 35 percent actual HCl; mix thoroughly and allow the solution to stand for at least thirty minutes. The finished solution must contain not less than 1 percent actual hydrochloric acid. (This solution may be utilized in the disinfection of casings as prescribed in § 96.12.)

(2) Dissolve the salt in the proportion of 90 pounds of salt to 100 gallons of water. Add 20 pounds of 95 percent to 98 percent sodium hydroxide (commercial "76 percent caustic soda") and stir until solution is complete; and allow it to stand for at least 30 minutes. (This solution may be utilized in the disinfection of casing containers as prescribed in paragraphs (a) (2) and (b) of this section.

(3) It is best to employ flaked caustic soda and not the variety which is very finely powdered. The fine powder is irritating and injurious to workers if it becomes suspended in the air. Containers of caustic soda should be kept tightly closed as the product deteriorates from contact with the air.

[28 FR 5986, June 13, 1963, as amended at 32 FR 19156, Dec. 20, 1967]

§ 96.10 Disinfecting plant and equipment for uncertified casings.

Uncertified foreign animal casings shall be disinfected only at a plant whose sanitation and disinfecting equipment have been approved by an inspector of Veterinary Services.

§ 96.11 Uncertified casings not disinfected in 30 days; disposition.

Foreign animal casings offered for importation without certification shall be disinfected as prescribed in § 96.12 within a period of 30 days after arrival in the United States, subject to the ability of Division inspectors to cover their respective districts. Otherwise such casings shall be exported or destroyed.

§ 96.12 Uncertified casings; disinfection with hydrochloric acid.

Foreign animal casings offered for importation into the United States without certification may be disinfected, as prescribed in this section, under the supervision of a Veterinary Services inspector for use as food containers, as an alternative for foreign certification.

(a) Disinfect the casings in a solution made as follows: Dissolve 90 pounds common salt in 100 gallons water and mix. Add 2¾ gallons (10.35 liters) C. P. hydrochloric acid containing not less than 35 percent actual HCl and mix throughly. The finished solution must contain not less than 1 percent actual hydrochloric acid.

(b) Containers of the disinfectant solution may be either of wood or of metal, but the interior surfaces must be protected by means of an acid resistant coating.

(c) Not more than 175 pounds casings shall be treated with each 100 gallons of the solution. After the treatment of 175 pounds of casings, or at the end of the day if less than 175 pounds of casings are disinfected in any one day, the solution shall be discarded unless means are provided for accurately determining the loss of strength. In event means for accurately determining loss of strength are provided it will be permissible to restore the strength of the solution with fresh acid and use it repeatedly.

(d) Shake as much of the adherent salt as possible from the casings and weigh them. Bundles must be separated but individual hanks need not be untied. Place the casings in the disinfecting solution a few hanks at a time with vigorous agitation to insure the fullest possible contact of the solution with them. Then keep the casings completely submerged in the solution for not less than three-fourths of an hour.

(e) Remove the casings from the solution, rinse them with water, and place them in a solution containing 8½ pounds of sodium bicarbonate in each 100 gallons of water. 100 gallons of this solution is sufficient for 175 pounds of casings. Keep the casings in this solution for 30 minutes, moving them about frequently and vigorously so as to insure complete contact of the solution with the casings. After this neutralization, remove the casings from the sodium bicarbonate solution and wash them to remove the excess of bicarbonate.

§ 96.13 Uncertified casings; disinfection with saturated brine solution.

Foreign animal casings offered for importation into the United States upon disinfection, may either be disinfected with hydrochloric acid as at present or if preferred may be submerged in a saturated brine solution at a temperature not less than 127° F. for at least 15 minutes. The time held as well as the temperature of such brine solution must be recorded on a one-hour dial of a recording thermometer and filed in the local Veterinary Services office for official inspection at any time. In order that this required temperature may be more readily maintained, such casings must first be submerged in a brine solution at approximately 127° F. for about five minutes immediately before the 15-minute recorded submersion period begins. This may be done either in the testing vat or a preliminary vat. By following this procedure the temperature will not vary unduly and thus cause unsatisfactory results. After removing the casings from the testing vat, it will be found advantageous to submerge them in another vat containing cold brine solution or cold water in order to remove the extra heat from the casings as promptly as possible, but of course this is optional with the importer. In order to obtain the most satisfactory results, the hanks, rings, and similar units must be separated as much as possible without untying, but "dolls" will not be permitted to be disinfected by this heating method. In order to keep the temperature of the brine in the testing vat of a uniform degree, it is necessary to agitate the solution occasionally by moving the casings. The tip of the recording thermometer should be located at a point which would be approximately at the bottom of the volume of casings being disinfected.

§ 96.14 Common carriers; marking papers.

Railroad companies, express companies, and other common carriers transporting foreign animal casings which have been released for entry shall mark the transportation papers accompanying the casings with the statement "Released by U.S. Customs."

§ 96.15 Form for reporting release.

MI Form 109-L, reporting the release of foreign animal casings, should be prepared in triplicate, the original copy, with foreign official certificate attached, shall be forwarded to Washington, the duplicate copy to the collector of customs at port of entry, and the triplicate copy retained for the station records.

PART 97—OVERTIME SERVICES RELATING TO IMPORTS AND EXPORTS

Sec.
97.1 Overtime work at laboratories, border ports, ocean ports, and airports.
97.2 Administrative instructions prescribing commuted traveltime.

AUTHORITY: 7 U.S.C. 2260; 49 U.S.C. 1741; 7 CFR 2.17, 2.51, and 371.2(d).

§ 97.1 Overtime work at laboratories, border ports, ocean ports, and airports.[1]

(a) Any person, firm, or corporation having ownership, custody, or control of animals, animal byproducts, or other commodities subject to inspection, laboratory testing, certification, or quarantine under this subchapter and Subchapter G of this Chapter, and who requires the services of an employee of Veterinary Services on a Sunday or holiday, or at any other time outside the regular tour of duty of such employee, shall sufficiently in advance of the period of Sunday or holiday or overtime service request the Veterinary Services inspector in charge to furnish inspection, laboratory testing, certification, or quarantine service during such overtime, or Sunday or holiday period, except as provided in paragraph (b) of this section, shall pay the Government therefor at a rate of $29.12 per work-hour per employee on a Sunday and at the rate of $22.48 per work-hour per employee for holiday or any other period; except that for any services performed on a Sunday or holiday, except as provided in paragraph (b) of this section for inspection or quarantine services requested by an owner or operator of an aircraft at an airport on a Sunday or holiday which are performed within regularly established hours of service, or at any time after 5 p.m. or before 8 a.m. on a weekday, in connection with the arrival in or departure from the United States of a private aircraft or vessel, the total amount payable shall not exceed $25 for all inspection services performed by the Customs Service, Immigration and Naturalization Service, Public Health Service, and the Department of Agriculture. A minimum charge of 2 hours shall be made for any Sunday or holiday or unscheduled overtime duty performed by an employee on a day when no work was scheduled for him or which is performed by an employee on his regular work day beginning either at least 1 hour before his scheduled tour of duty or which is not in direct continuation of the employee's regular tour of duty. In addition, each such period of Sunday or holiday or unscheduled overtime work to which the 2-hour minimum charge applies may include a commuted traveltime period (CTT) the amount of which shall be prescribed in administrative instructions to be issued by the Deputy Administrator, Veterinary Services for the areas in which the Sunday or holiday or overtime work is performed and such period shall be established as nearly as may be practicable to cover the time necessarily spent in reporting to and returning from the place at which the employee performs such Sunday, holiday or overtime duty. With respect to places of duty within the metropolitan area of the employee's headquarters, such CTT period shall not exceed 3 hours. It shall be administratively determined from time to time which days constitute holidays. The circumstances under which such CTT periods shall be charged and the percentage applicable in each circumstance are as reflected in the following table:

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[1] For designated ports of entry for certain animals, animal semen, poultry, and hatching eggs see 9 CFR 92.1 through 92.3 and for designated ports of entry for certain purebred animals see 9 CFR 151.1 through 151.3.

	Actual time [1] charge—no minimum	2-hour guarantee charge	Commuted [2] traveltime (CTT) charge
Charges for Inspection Within Metropolitan Area of Employee's Headquarters			
Work beginning before daily tour begins:			
8 to 59 minutes.	Yes	No	None.
60 to 119 minutes.		Yes	½ CTT.
120 minutes or more.		Yes	Full CTT.
Work beginning after daily tour ends:			
Direct continuation.	Yes	No	None.
Break-in-service of:			
2–29 minutes		Yes	None.
30–60 minutes		Yes	½ CTT.
61 minutes or more.		Yes	Full CTT.
Charges for Inspection Services Performed Outside Metropolitan Area of Employee's Headquarters			
Work beginning before daily tour begins:			
8 to 59 minutes.	Yes	No	½ CTT.
60 minutes or more.		Yes	Full CTT.
Work beginning after daily tour ends:			
Direct continuations.	Yes	No	½ CTT.
2–59 minutes	No	Yes	½ CTT.
60 minutes or more.	No	Yes	Full CTT.
Charges for Call Out Inspection Service on Holiday or Nonworkday			
Work beginning at any time.	No	Yes	Full CTT.

[1] Actual time charged when work is contiguous with the daily tour will be in quarter hour multiples, with service time of 8 minutes or more rounded up to the next quarter hour and any time of less than 8 minutes will be disregarded.

[2] The full CTT allowance will be the amount of commuted traveltime prescribed for the place at which the inspections are performed. See Part 97.2. One-half CTT is ½ of the full CTT period.

(b) Any owner or operator of an aircraft requesting inspection services or quarantine services at an airport during regularly established hours of service on a Sunday or holiday shall be provided service without reimbursement as if such service had been performed during regularly established hours of service on weekdays. When services are performed outside of the regularly established hours of service on a holiday or Sunday or any other day, the rate to be charged owners or operators of aircraft shall be $24.52 per hour on a Sunday and $17.28 per hour on a holiday or any other day, which charges exclude administrative overhead costs.

(c) As used in this section—

(1) The term "private aircraft" means any civilian aircraft not being used to transport persons or property for compensation or hire, and

(2) The term "private vessel" means any civilian vessel not being used (i) to transport persons or property for compensation or hire, or (ii) in fishing operations or in processing of fish or fish products.

[38 FR 28814, Oct. 17, 1973, as amended at 42 FR 1455, Jan. 7, 1977; 49 FR 1176, Jan. 10, 1984; 49 FR 12191, Mar. 29, 1984; 50 FR 723, Jan. 7, 1985]

§ 97.2 Administrative instructions prescribing commuted traveltime.

Each period of overtime and holiday duty as prescribed in § 97.1 shall in addition include a commuted traveltime period for the respective ports, stations, and areas in which employees are located. The prescribed computed traveltime periods are as follows:

COMMUTED TRAVELTIME ALLOWANCES

[In hours]

Location covered	Served from	Metropolitan Area	
		Within	Outside
Alaska:			
Anchorage		1	
Do	Palmer		3
Arizona:			
Douglas		1	
Do	Nogales		6
Naco	Douglas		2
Nogales		1	
Do	Douglas		6
Do	Tucson		3
San Luis	Yuma		2
Sasabe	Nogales		4
Do	Tuscon		3
California:			
Calexico	San Ysidro		3
Edwards Air Force Base.	Los Angeles		4
Los Angeles and Los Angeles International Airport.	San Bernardino		5
Do	Los Angeles	2	
Los Angeles Harbor, San Pedro, including Long Beach, Wilmington, and Terminal Island.	Los Angeles		2
March Field	do		5
Newport Beach	do		4
Ontario	do		3
Ramona	San Ysidro		2
Sacramento		1	
Do	San Francisco		5
San Diego		1	
Do	San Ysidro		2
San Francisco including, Alameda, Richmond, Pittsburg, and other ports in San Francisco and San Pablo Bay areas.		2	
San Louis Obispo.	San Pedro		6
San Ysidro		1	
Stockton	San Francisco		4
Colorado:			
Stapleton International Airport, Denver.	Arvada	1	
Do	Aurora		2
Connecticut:			
Bradley International Airport, Windsor Locks.	Ashford		1
Do	East Providence, RI.		4
Do	Harwinton		2
Do	Stockbridge and East Brookfield, MA.		3
Do	Hartford	2	
Do	Storrs		3
Delaware:			
Wilmington	Dover		3
Florida:			
Jacksonville		2	
Miami		2	
Port Everglades	Miami		2
St. Petersburg	Tampa		2
Do	Miami		6
Tampa		2	

COMMUTED TRAVELTIME ALLOWANCES—Continued

[In hours]

Location covered	Served from	Metropolitan Area	
		Within	Outside
Do	Miami		6
Georgia:			
Port of Brunswick.	Savannah		4
Port of Savannah.	do	2	
Port of St. Mary's.	do		6
Hawaii:			
Kawaihae	Waimea		1
Hilo	do		3
Honolulu, including Aiea, Barber's Point Naval Air Station, Honolulu International Airport, West Loch, Middle Loch, East Loch, Pearl City and Waipahu.		2	
Idaho:			
Boise	Caldwell or Middleton.		2
Eastport	Bonners Ferry		2
Do	Spokane, WA		6
Illinois:			
Bloomington	Pana		3
Do	Springfield		3
Do	Tolono		3
Camp Grove	El Paso		3
Do	Springfield		5
Chicago		3	
Peoria	El Paso		2
Do	Springfield		3
Do	Tolono		4
Springfield	El Paso		3
Do	Nebo		3
Do	Pana		2
Do	Tolono		3
Indiana:			
Indianapolis		1	
Do	Anderson		2
Do	West Lafayette		3
Iowa:			
Ames		1	
Kentucky:			
Standiford Field	Frankfort		3
Do	Louisville	1	
Louisiana:			
Acadian Regional Airport, New Iberia.	Abbeville		2
Any point below Chalmette and on the East Bank, Belle Chasse, LA, and points to and including Port Sulphur on the west bank.	Baton Rouge		4
Any point on the Mississippi River above the St. Charles-Jefferson Parish boundary to and including Gramercy.	do		2
Morgan City	do		5
New Orleans including Orleans Parish and all points on the east bank of the Mississippi River from the St. Charles-Jefferson Parish boundary to and including Chalmette, LA, and all points on the west bank from the St. Charles-Jefferson Parish boundary to but excluding Belle Chasse, LA.	do		4
Undesignated ports.	do		3
Maine:			
Bangor	Augusta		3
Do	Carmel		1
Jackman	Bangor		5
Houlton		1	
Port of Portland	Augusta		3
Do	Bangor		6
Do	Concord, NH		4
Maryland:			
Baltimore:		3	
Largo	Bowie	2	
Do	Owings Mills	3	
Do	Easton		4
Laurel	Bowie	2	

COMMUTED TRAVELTIME ALLOWANCES—Continued

[In hours]

Location covered	Served from	Metropolitan Area	
		Within	Outside
Do	Owings Mills	3	
Do	Easton		4
Massachusetts:			
Boston		3	
Michigan:			
Detroit	Blissfield and Port Huron.		3
Port Huron	Detroit		3
Do	Saginaw		4
Minnesota:			
Minneapolis/St. Paul International Airport.		2	
Do	Rochester		3
Do	Princeton		3
Noyes	Pembina		1
Missouri:			
Kansas City International Airport.	Jefferson		6
St. Louis Airport	Beaufort		3
St. Louis Zoological Park.	do		3
Montana:			
Bozeman		1	
Great Falls Airport.	Vaughn	1	
Port of Opheim	Opheim		1
Do.	Wolf Point		5
Port of Raymond.	Raymond		1
Port of Sweetgrass.	Great Falls		5
Sweetgrass		1	
Nebraska:			
Lincoln Airport		1	
New Mexico:			
Antelope Wells		1	
Do	Deming		5
Do	Hachita		3
Do	Las Cruces		8
Do	Roswell and Socorro.		6
Columbus		1	
Do	El Paso, TX		5
Do	Hachita		3
Do	Las Cruces		4
Do	Roswell and Socorro.		6
Port of Columbus.	Deming		2
New York:			
Alexandria Bay		1	
Buffalo		2	
Do	Akron		2
Champlain		1	
Malone	Champlain		3
Newburgh		1	
Do	New York, NY		4
New York		3	
Niagara Falls	Akron		2
Odgensburg		1	
Port of Albany		1	
Rochester	Buffalo		4
Roosevelttown	Odgensburg		2
Rouses Point	Champlain		1
Stewart Airport, Newburgh.	Albany		4
North Dakota:			
Dunseith	Minot		4
Do	Pembina		6
Minot		1	
Peace Gardens	Bottineau		1
Pembina		1	
Do	Fargo		6
Portal		1	
Do	Dickinson		6
Do	Minot		4
Oregon:			
Portland	Canby		3
Do	Salem		3
Do	Troutsdale	2	
Pennsylvania:			
Harrisburg	Camp Hill	1	
Do	Morgantown		3
Do	Northumberland		2
Do	Shippensburg		3
Philadelphia		3	
Puerto Rico:			
Aquadilla	Aquadilla		2
Salinas	San Juan		4
San Juan		2	
Texas:			
Brownsville		1	
Do	Laredo or San Antonio.		6
Brownsville and Brownsville International Airport.	Harlingen and San Benito.		1
Do	McAllen or Edinburg.		3
Do	Weslaco		2
Dallas-Ft. Worth International Airport.	Ft. Worth or Dallas.		2
Del Rio		1	
Do	Eagle Pass		3
Do	Edinburg, McAllen or Mission.		8
Do	Laredo or San Antonio.		5
Eagle Pass		1	
Do	Del Rio		3
Do	Edinburgh, McAllen or Mission.		6
Do	Laredo or San Antonio.		5
El Paso		1	
Do	Hatchita or Deming, NM.		6
Do	Las Crucres, NM		3
Harlingen	Edinburg, McAllen or Mission.		2
Do	Weslaco		1
Hidalgo	Brownsville		3
Do	Edinburg, Mission and McAllen.		1

COMMUTED TRAVELTIME ALLOWANCES—Continued

[In hours]

Location covered	Served from	Metropolitan Area	
		Within	Outside
Do	Rio Grande City		2
Houston (except Houston Intercontinental Airport).		2	
Houston Intercontinental Airport.		3	
Laredo		1	
Do	Brownsville or San Antonio.		6
Do	Eagle Pass		5
Do	McAllen, Edinburg or Mission.		6
Presidio		1	
Do	El Paso		6
Utah:			
Salt Lake City	Murray and Ogden.	2	
Vermont:			
Burlington International Airport.	Burlington	1	
Do	Highgate Springs		2
Do	Montpelier		2
Derby Line	St. Albans		4
Highgate Springs.	do		1
Virginia:			
Dulles International Airport.	Hyattsville, MD	3	
Do	Richmond		5
Do	Warrenton		3
Port of Richmond.		2	
Washington:			
Blaine		1	
Do	Seattle		6
Lynden	Blaine		2
Do	Seattle		6
Moses Lake	Oroville, WA		6
Do	Spokane		5
Do	Wenatchee		3
Do	Yakima		4
Oroville		1	
Sea-Tac Airport	Olympia		3
Seattle		2	
Sumas	Blaine		2
Do	Seattle		6
Tacoma	do		3
Wisconsin:			
Barron	Ripon		6
Madison		1	
Monroe	Madison		3

[39 FR 41356, Nov. 27, 1974]

EDITORIAL NOTE: For Federal Register citations affecting § 97.2, see the List of CFR Sections Affected in the Finding Aids section of this volume.

PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS

Sec.
98.1 Definitions.
98.2 Prohibition.
98.3 General conditions.
98.4 Import permit.
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98.6 Ports of entry.
98.7 Declaration upon arrival.
98.8 Inspection.
98.9 Embryos refused entry.
98.10 Other importations.

AUTHORITY: 21 U.S.C. 103, 104, 105, 111, 134a, 134b, 134c, 134d, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 50 FR 43563, Oct. 25, 1985, unless otherwise noted.

§ 98.1 Definitions.

The following terms, when used in this part, shall be construed as defined. Those terms used in the singular form in this part shall be construed as the plural form and vice versa, as the case may demand.

Animal. Any cattle, sheep, goats, other ruminants, swine, horses, or asses.

Approved artificial insemination center. A facility approved or licensed by the government of the country in which the facility is located to collect and process semen under the general supervision of such government.

Approved embryo transfer unit. A facility approved or licensed by the government of the country in which the facility is located for the artificial insemination of donor dams or for conception as a result of natural breeding by a donor sire and for collecting and processing embryos for export under the general supervision of such government.

Department. The United States Department of Agriculture.

Deputy Administrator. The Deputy Administrator, Veterinary Services, or any official in the Veterinary Services unit of the Animal and Plant Health Inspection Service of the Department to whom authority has been delegated or may hereafter be delegated to act in the Deputy Administrator's stead.

Embryo. The initial stage of an animal's development after collection from the natural mother, while it is capable of being transferred to a recipient dam, but not including an embryo that has been transferred to a recipient dam.

Enter (entered, entry) into the United States. To introduce into the commerce of the United States after release from governmental detention at the port of entry.

Import (imported, importation) into the United States. To bring into the territorial limits of the United States.

Inspector. An employee of Veterinary Services who is authorized to perform the function involved.

Person. Any individual, corporation, company, association, firm, partnership, society, joint stock company, or any other legal entity.

United States. All of the several States of the United States, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States and all other territories and possessions of the United States.

Veterinary Services. The Veterinary Services unit of the Animal and Plant Health Inspection Service of the Department.

§ 98.2 Prohibition.

An embryo shall not be imported or entered into the United States unless in accordance with the provisions of this part.

§ 98.3 General conditions.

An embryo shall not be imported into the United States unless:

(a) The embryo is exported to the United States from the country in which it was conceived;

(b) The embryo was conceived as a result of artificial insemination with semen collected from a donor sire at an approved artificial insemination center, or the embryo as conceived as a result of natural breeding by a donor sire at an approved embryo transfer unit;

(c) If artificially inseminated, the donor dam conceived the embryo after being inseminated in an approved embryo transfer unit with semen collected at an approved artificial insemination center;

(d) At the time of collection of the semen used to conceive the embryo or at the time of natural breeding, the donor sire met all requirements the donor sire would have to meet under Part 92 of this chapter for a health certificate required as a condition of importation into the United States;

(e) At the time of collection of the embryo from the donor dam, the donor dam met all requirements the donor dam would have to meet under Part 92 of this chapter for a health certificate required as a condition of importation into the United States;

(f) There is no basis for denying an import permit for the donor sire or donor dam under § 92.4(a) (2) or (3) of this chapter;

(g) The embryo is collected and maintained under conditions determined by the Deputy Administrator to be adequate to protect against contamination of the embryo with infectious animal disease organisms; and

(h) The embryo was determined, based on microscopic examination, to have an intact zona pellucida at the time the embryo was placed into its immediate container (straw or ampule) for shipping.

(i) The embryo is contained in a shipping container which at the time of offer for entry is sealed with an official seal which was affixed to the shipping container by a full-time salaried veterinarian of the national animal health service of the country of origin or by a veterinarian authorized to do so by the national animal health service of the country of origin.

§ 98.4 Import permit.

(a) An embryo shall not be imported into the United States unless accompanied by an import permit issued by Veterinary Services and unless imported into the United States within 14 days after the proposed date of arrival stated in the import permit.

(b) An application for an import permit must be submitted to Import-Export Animals and Products Staff, Veterinary Services, APHIS, USDA, Federal Building, 6505 Belcrest Road, Hyattsville MD 20782. An application form for an import permit may be obtained from this staff.

(c) The completed application shall include the following information:

(1) The name and address of the person intending to export an embryo from the country of origin,

(2) The name and address of the person intending to import an embryo,

(3) The species, breed, and number of embryos to be imported,

(4) The purpose of the importation,

(5) The country in which the embryo is conceived,

(6) The port of embarkation,

(7) The mode of transportation,

(8) The route of travel,

(9) The port of entry in the United States,

(10) The proposed date of arrival in the United States,

(11) The name and address of the person to whom the embryo will be delivered in the United States, and

(12) The measures to be taken to ensure that the embryo is collected and maintained under conditions adequate to protect against contamination of the embryo with infectious animal disease organisms.

(d) After receipt and review of the application by Veterinary Services, an import permit indicating the applicable conditions under this part for importation into the United States shall be issued for the importation of embryos described in the application if such embryos appear to be eligible to be imported. Even though an import permit has been issued for the importation of an embryo, the embryo may be imported only if all applicable requirements of this part are met.

§ 98.5 Health certificate.

An embryo shall not be imported into the United States unless accompanied by a health certificate issued by a full-time salaried veterinarian of the national animal health service of the country of origin *or* signed by a veterinarian authorized by the national animal health service of the country of origin and endorsed by a salaried veterinarian of the national animal health service of the country of origin (the endorsement representing that the veterinarian signing the health certificate was authorized to do so), certifying:

(a) The dates, places, types, and results of all examinations and tests performed on the donor sire and donor dam as a condition for importation of the embryo, and the names and addresses of persons or laboratories conducting the examinations or tests, and a statement that any other requirements established by § 98.3 have been complied with,

(b) The name and address of the consignor and consignee,

(c) The name and address of the approved artificial insemination center where the semen for the embryo was collected, if applicable,

(d) The name and address of the approved embryo transfer unit where the donor dam was inseminated or bred and the embryo was collected, and

(e) The measures taken to ensure that the embryo was collected and maintained under conditions adequate to protect against contamination of the embryo with infectious animal disease organisms.

§ 98.6 Ports of entry.

An embryo shall not be imported into the United States unless at a port of entry listed in § 92.3 of this chapter.

§ 98.7 Declaration upon arrival.

Upon arrival of an embryo at a port of entry, the importer or the importer's agent shall notify Veterinary Services of the arrival by giving an inspector a document stating:

(a) The port of entry,

(b) The date of arrival,

(c) Import permit number,

(d) Carrier, and identification of the means of conveyance,

(e) The name and address of the importer,

(f) The name and address of the broker,

(g) The country of origin of the embryo,

(h) The number, species, and purpose of importation of the embryo, and

(i) The name and address of the person to whom the embryo will be delivered.

§ 98.8 Inspection.

Any embryo offered for entry into the United States and documents accompanying the embryo shall be subject to inspection by an inspector at the time the embryo is offered for entry in order to determine whether the embryo is eligible for entry. The import permit and the health certificate shall be given to the inspector.

§ 98.9 Embryos refused entry.

Any embryo refused entry into the United States for noncompliance with the requirements of this part shall be removed from the United States within a time period specified by the Deputy Administrator or abandoned by the importer for destruction, and pending such action shall be subject to such safeguards as the inspector determines necessary to prevent the possible introduction into the United States of infectious animal diseases. If such embryo is not removed from the United States within such time period, or abandoned for destruction, it may be seized, destroyed, or otherwise disposed of as the inspector determines necessary to prevent the possible introduction into the United States of infectious animal diseases.

§ 98.10 Other importations.

Notwithstanding other provisions in this part, the Deputy Administrator may in specific cases allow the importation and entry into the United States of embryos other than as provided for in this part under such conditions as the Deputy Administrator may prescribe to prevent the introduction into the United States of infectious animal diseases.

SUBCHAPTER E—VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS; ORGANISMS AND VECTORS

PART 101—DEFINITIONS

Sec.

101.1 Applicability.
101.2 Administrative terminology.
101.3 Biological products and related terms.
101.4 Labeling terminology.
101.5 Testing terminology.
101.6 Cell cultures.
101.7 Seed organisms.

AUTHORITY: 21 U.S.C. 151-158; 37 FR 28477, 28646; 38 FR 19141.

SOURCE: 38 FR 8426, Apr. 2, 1973, unless otherwise noted.

§ 101.1 Applicability.

When used in Parts 101 through 117 of this subchapter, the meaning of the words and phrases listed shall be as defined in this part.

§ 101.2 Administrative terminology.

The following administrative words and phrases shall mean:

(a) *Virus-Serum-Toxin Act.* The virus, serum, toxin, and analogous products provisions of the Act of Congress of March 4, 1913, 37 Stat. 832-833, 21 U.S.C. 151-158.

(b) *Regulations.* The provisions in Parts 101 through 117 of this subchapter.

(c) *Domestic animals.* All animals, other than man, including poultry.

(d) *Department.* The U.S. Department of Agriculture.

(e) *Secretary.* The Secretary of Agriculture of the United States or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

(f) *Veterinary Services.* Veterinary Services unit of Animal and Plant Health Inspection Service of the Department.

(g) *Deputy Administrator.* The Deputy Administrator, Veterinary Services, or any officer or employee of the Veterinary Services to whom authority has heretofore lawfully been delegated, or to whom authority may hereafter lawfully be delegated, to act in his stead.

(h) *Inspector.* Any officer or employee of Veterinary Services who is authorized by the Deputy Administrator to do inspection work.

(i) *Inspection.* An examination made by an inspector to determine the fitness of animals, establishments, facilities, and procedures used in connection with the preparation, testing, and distribution of biological products and the examination or testing of biological products.

(j) *Person.* Any individual, firm, partnership, corporation, company, association, educational institution, State or local governmental agency, or other organized group of any of the foregoing, or any agent, officer, or employee of any thereof.

(k) *Subsidiary.* A corporation in which a corporate licensee owns in excess of 50 percent of the voting stock.

(l) *Distributor.* A person who sells, distributes, or otherwise places in channels of trade, one or more biological products he does not produce or import.

(m) *Licensee.* A person to whom an establishment license and at least one product license has been issued.

(n) *Permittee.* A person who resides in the United States or operates a business establishment within the United States, to whom a permit to import biological products has been issued.

(o) *Research investigator or research sponsor.* A person who has requested authorization to make interstate movements of an experimental biological product for the purpose of evaluating such product as provided for in Part 103 of this subchapter or has been granted such authorization.

(p) *Premises.* All buildings, appurtenances, and equipment used to produce and store biological products located within a particular land area shown on building plans or drawings furnished by the applicant or the licensee and designated by an address adequate for identification.

(q) *Establishment.* One or more premises designated on the establishment license.

(r) *U.S. Veterinary Biologics Establishment License.* A document referred to as an establishment license, which is issued pursuant to Part 102 of this subchapter, authorizing the use of designated premises for production of biological products specified in one or more unexpired, unsuspended, and unrevoked product license(s).

(s) *Licensed establishment.* An establishment operated by a person holding an unexpired, unsuspended, and unrevoked U.S. Veterinary Biologics Establishment License.

(t) *U.S. Veterinary Biological Product License.* A document, sometimes referred to as a product license, which is issued pursuant to Part 102 of this subchapter to the holder of an establishment license, as a part of and ancillary to the establishment license, and which authorizes production of a specified biological product in the designated licensed establishment.

(u) [Reserved]

(v) *U.S. Veterinary Biological Product Permit.* A document, sometimes referred to as a permit, issued to a person authorizing the importation of specified biological products subject to restrictions and controls as provided in the regulations.

(w) *Biological products.* The term biological products, sometimes referred to as biologics, biologicals, or products, shall mean all viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

(x) *Microorganisms.* Microscopic or submicroscopic organisms, which are sometimes referred to as organisms, which may introduce or disseminate disease of animals.

(y) *Prepare or preparation.* Sometimes referred to as manufacture or produce, means the steps and procedures used in the processing, testing, packaging, labeling, and storing of a biological product.

(z) *Division.* A marketing unit established by the licensee which may be named on labels, advertisements and promotional material in addition to the name and address of the producer.

[38 FR 8426, Apr. 2, 1973; 38 FR 9221, Apr. 12, 1973, as amended at 40 FR 46093, Oct. 6, 1975; 41 FR 44358, Oct. 8, 1976; 49 FR 22624, May 31, 1984]

§ 101.3 Biological products and related terms.

When used in conjunction with or in reference to a biological product, the following terms shall mean:

(a) *Licensed biological product.* A biological product prepared within a licensed establishment by a person holding an unexpired, unsuspended, and unrevoked product license for such product.

(b) *Experimental biological product.* A biological product which is being evaluated to substantiate an application for a product license or permit.

(c) *Completed product.* A biological product in bulk or final container produced in compliance with the regulations to final form and composition.

(d) *Finished product.* A completed product which has been bottled, sealed, packaged, and labeled as required by the regulations.

(e) *Released product.* A finished product released for marketing after all requirements have been satisfactorily complied with.

(f) *Fraction.* A specific antigen, its antibodies, or its antitoxin which constitutes a component of a biological product.

(g) *Diluent.* A liquid used to rehydrate a desiccated product or a liquid used to dilute another substance.

(h) *Serial.* The total quantity of completed product which has been thoroughly mixed in a single container and identified by a serial number: *Provided,* That, when all or part of a serial of liquid biological product is packaged as diluent for all or part of a serial of desiccated product, the resulting combination packages shall be considered a serial of the multiple fraction product.

(i) *Subserial.* Each of two or more properly identified portions of a serial which are further processed at different times or under different conditions such as, but not limited to, being desiccated in different size final containers and/or at different times.

(j) *Outline of production.* A detailed protocol of methods of manufacture to be followed in the preparation of a biological product and which may sometimes be referred to as an outline.

(k) *Product Code Number.* A number assigned by Veterinary Services to each type of licensed biological product.

(l) *Harvest date.* Unless otherwise specified in a filed Outline of Production, the harvest date shall be the date blood or tissues are collected for production or the date cultures of living microorganisms are removed from production incubators.

[38 FR 8426, Apr. 2, 1973, as amended at 42 FR 63770, Dec. 20, 1977; 50 FR 24903, June 14, 1985]

§ 101.4 Labeling terminology.

Terms pertaining to identification and packaging of biological products shall mean:

(a) *Label.* All written, graphic, or printed matter:

(1) Upon or attached to a final container of a biological product;

(2) Appearing upon any immediate carton or box used to package such final container; and

(3) Appearing on any accompanying enclosures (leaflets, inserts, or circulars) on which required information or directions as to the use of the biological product shall be found.

(b) *Labeling.* All labels and other written, printed, or graphic matter accompanying the final container.

(c) *Final container.* The unit, bottle, vial, ampule, tube, or other receptacle into which any biological product is filled for distribution and sale.

(d) *True name.* The name entered on the product license or permit at the time of issuance to differentiate the biological product from others: *Provided,* That, the principal part of such name shall be emphasized on such license or permit by being more prominently lettered than descriptive terms which may be necessary to complete the differentiation.

(e) *Serial number.* Numbers or numbers and letters used to identify and distinguish one serial from others.

(f) *Expiration date.* A date designating the end of the period during which a biological product, when properly stored and handled, can be expected with reasonable certainty, to be efficacious.

(g) *Label number.* A number assigned by Veterinary Services to each label or sketch submitted for review.

[38 FR 8426, Apr. 2, 1973, as amended at 42 FR 63770, Dec. 20, 1977]

§ 101.5 Testing terminology.

Terms used when evaluating biological products shall mean:

(a) *Standard Requirement.* Test methods, procedures, and criteria established by Veterinary Services for evaluating biological products to be pure, safe, potent, and efficacious, and not to be worthless, contaminated, dangerous, or harmful under the Act.

(b) *Log.* Logarithm computed to the base 10.

(c) *Pure or purity.* Quality of a biological product prepared to a final form relatively free of extraneous micro-organisms and extraneous material (organic or inorganic) as determined by test methods or procedures established by Veterinary Services in Standard Requirements or in the approved Outline of Production for such product, but free of extraneous microorganisms or material which in the opinion of the Deputy Administrator adversely affects the safety, potency, or efficacy of such product.

(d) *Safe or safety.* Freedom from properties causing undue local or systemic reactions when used as recommended or suggested by the manufacturer.

(e) *Sterile or sterility.* Freedom from viable contaminating microorganisms as demonstrated by procedures prescribed in Part 113 of this subchapter, Standard Requirements, and approved Outlines of Production.

(f) *Potent or potency.* Relative strength of a biological product as determined by test methods or procedures as established by Veterinary Services in Standard Requirements or in the approved Outline of Production for such product.

(g) *Efficacious or efficacy.* Specific ability or capacity of the biological product to effect the result for which it is offered when used under the conditions recommended by the manufacturer.

(h) *Dose.* The amount of a biological product recommended on the label to be given to one animal at one time.

(i) *Vaccinate.* An animal which has been inoculated, injected, or otherwise administered a biological product being evaluated.

(j) *Control animal.* An animal, which may be referred to as a control, used in a test procedure for purposes of comparison or to add validity to the results.

(k) *Day.* Time elapsing between any regular working hour of one day and any regular working hour of the following day.

(l) *No test.* A test which produces inconclusive or invalid results and therefore, cannot be used to evaluate a biological product.

(m) *Healthy.* Apparently normal in all vital functions and free of signs of disease.

(n) *Unfavorable reactions.* Overt adverse changes which occur in healthy test animals subsequent to initiation of a test and manifested during the observation period prescribed in the test protocol which are attributable either to the biological product being tested or to factors unrelated to such product as determined by the responsible individual conducting the test.

[38 FR 8426, Apr. 2, 1973, as amended at 40 FR 45419, Oct. 2, 1975; 41 FR 6751, Feb. 13, 1976; 43 FR 3701, Jan. 27, 1978]

§ 101.6 Cell cultures.

When used in conjunction with or in reference to cell cultures, which may be referred to as tissue cultures, the following terms shall mean:

(a) *Batches of primary cells.* A pool of original cells derived from normal tissue up to and including the 10th subculture.

(b) *Cell line.* A pool of cells which are 11 or more subcultures from the tissue of origin.

(c) *Subculture.* Each flask to flask transfer or passage regardless of the number of cell replications.

(d) *Master Cell Stock (MCS).* The supply of cells of a specific passage level from which cells for production of biologics originate.

[38 FR 8426, Apr. 2, 1973, as amended at 40 FR 45419, Oct. 2, 1975; 49 FR 22624, May 31, 1984]

§ 101.7 Seed organisms.

When used in conjunction with or in reference to seed organisms, the following shall mean:

(a) *Master Seed.* An organism at a specific passage level which has been selected and permanently stored by the producer from which all other seed passages are derived within permitted levels.

(b) *Working Seed.* An organism at a passage level between Master Seed and Production Seed.

(c) *Production Seed.* An organism at a specified passage level which is used without further propagation for initiating preparation of a fraction.

[49 FR 22625, May 31, 1984]

PART 102—LICENSES FOR BIOLOGICAL PRODUCTS

Sec.
102.1 Licenses issued by the Deputy Administrator.
102.2 Licenses required.
102.3 License applications.
102.4 U.S. Veterinary Biologics Establishment License.
102.5 U.S. Veterinary Biological Product License.

AUTHORITY: 21 U.S.C. 151-158; 7 CFR 2.17, 2.51, and 371.2(d).

§ 102.1 Licenses issued by the Deputy Administrator.

Each establishment qualified to produce biological products under the Virus-Serum-Toxin Act shall hold an unexpired and unrevoked U.S. Veterinary Biologics Establishment License issued by the Deputy Administrator and a U.S. Veterinary Biological Product License for each product prepared in such establishment unless the establishment is licensed for an interim period as provided in § 102.4(h) of this

Subchapter or unless the product is subject to the provisions of Parts 103 or 106 of this Subchapter.

[50 FR 50763, Dec. 12, 1985]

§ 102.2 Licenses required.

Every person who prepares biological products subject to the Virus-Serum-Toxin Act shall hold an unexpired, unsuspended, and unrevoked U.S. Veterinary Biologics Establishment License and at least one unexpired, unsuspended, and unrevoked U.S. Veterinary Biological Product License issued by the Deputy Administrator to prepare a biological product other than an autogenous biologic in such establishment: *Provided*, That, if the applicant for an establishment license wishes to prepare an autogenous biologic, then a nonautogenous biological product must be licensed for production in such establishment in order to meet the requirements of this section.

[41 FR 44358, Oct. 8, 1976]

§ 102.3 License applications.

(a) *U.S. Veterinary Biologics Establishment License.* (1) The operator of each establishment of the kind specified in § 102.2 shall make written application to the Deputy Administrator for a license. Blank forms of application will be furnished upon request to Veterinary Services.

(2) When a person conducts more than one establishment, a separate application shall be made for each establishment.

(3) Whenever subsidiaries are to operate in an establishment for which license application is made, the applicant shall apply for permission for such subsidiaries to operate in the establishment and furnish therewith a complete statement regarding the relationship between the applicant and the subsidiaries.

(4) Facilities documents, prepared as prescribed in Part 108 of this subchapter, shall accompany the application for license unless previously filed with Veterinary Services.

(5) Each application for a U.S. Veterinary Biologics Establishment License shall be accompanied by an application for one or more U.S. Veterinary Biological Product Licenses and the supporting documents required by paragraph (b)(2) of this section.

(6) A new application shall be made when a change of ownership, operation, or location of an establishment occurs; or prior to the expiration of a U.S. Veterinary Biologics Establishment License issued for an interim period of time.

(b) *U.S. Veterinary Biological Product License.* (1) The licensee of each establishment or applicant for an establishment license shall make written application to the Deputy Administrator for a U.S. Veterinary Biological Product License for each biological product to be prepared in the licensed establishment.

(2) Each application for a U.S. Veterinary Biological Product License shall be supported by:

(i) At least four copies of an Outline of Production prepared in accordance with §§ 114.8 and 114.9 of this subchapter; and

(ii) At least three copies of test reports and research data sufficient to establish purity, safety, potency, and efficacy of the product; and

(iii) Legends prepared as prescribed in § 108.5 of this subchapter designating which facilities are to be used in the preparation of each fraction; and

(iv) Labels in finished form or sketches prepared as prescribed in § 112.5 of this subchapter, together with information regarding all claims to be made on labels and in advertising matter to be used in connection with or related to the biological product.

(Approved by the Office of Management and Budget under control number 0579-0013)

[39 FR 37763, Oct. 24, 1974, as amended at 48 FR 57472, Dec. 30, 1983; 49 FR 21043, May 18, 1984; 50 FR 50763, Dec. 12, 1985]

§ 102.4 U.S. Veterinary Biologics Establishment License.

(a) Before a U.S. Veterinary Biologics Establishment License will be issued by the Deputy Administrator for any establishment, an inspection shall be made to determine whether the condition, equipment, facilities, and the like, of the establishment, and the methods used to prepare biological products are in conformity with the requirements in the regulations.

(b) A license shall not be issued unless:

(1) In the opinion of the Deputy Administrator, the condition of the establishment, including its facilities, and the methods of preparation of biological products are such as reasonably to assure that the products shall accomplish the purpose for which they are intended; and

(2) The Deputy Administrator is satisfied on the basis of information before him that:

(i) The establishment shall be operated in compliance with the Act and applicable regulations and be under the supervision of person(s) competent in the preparation of biological products; and

(ii) The applicant, or the person having the responsibility for producing biological products in the establishment, or both, is qualified by education and experience, and has demonstrated fitness to produce such products in compliance with the Act and regulations issued pursuant thereto; *Provided*, That, previous violations of the Act, or such regulations or both shall be relevant to the Deputy Administrator's determination of fitness.

(3) Written assurance is filed with Veterinary Services that the biological products which are licensed to be prepared therein shall not be so advertised as to mislead or deceive the purchasers and that the packages or containers in which the same are to be marketed shall not bear any statement, design, or device which is false or misleading in any particular.

(c) U.S. Veterinary Biologics Establishment Licenses shall be numbered and shall be in the following form:

U.S. VETERINARY BIOLOGICS ESTABLISHMENT LICENSE

No. ———,

Washington, D.C., ————.

This is to certify that, pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832) governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals ———— is hereby authorized to maintain at ———— an establishment for the preparation of biological products specified in one or more unexpired, unsuspended, and unrevoked product licenses and designated to be produced in this establishment. This license is subject to termination as provided in the regulations made under the authority contained in said Act, and to suspension of revocation if the licensee violates or fails to comply with said Act or the regulations made thereunder.

————————————.

Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

(d) Two or more licenses may bear the same number when they are issued for establishments under the same ownership or control, provided a serial letter is added to one or more to identify each license and the product produced thereunder.

(e) When a U.S. Veterinary Biologics Establishment License is issued for an establishment, it shall not apply to more than one person at the same location, except that subsidiaries of the licensee, when named in the license, may operate thereunder at the establishment named. The licensee with its subsidiaries will be held responsible for all operations conducted in the licensed establishment.

(f) When a licensee no longer holds an unexpired, unsuspended, or unrevoked product license authorizing the preparation of a biological product other than an autogenous biologic, any establishment license and any product licenses for autogenous biologics shall be submitted to the Deputy Administrator for termination.

(g) The provisions of paragraph (b) of this section shall also be applicable to, and be considered by, the Deputy Administrator in connection with each application for an additional product license.

(h) An establishment preparing unlicensed veterinary biological products for intrastate distribution which qualifies for the issuance of a U.S. Veterinary Biologics Establishment License and one or more U.S. Veterinary Biological Product Licenses and which desires to continue producing the unlicensed products, may be issued a U.S. Veterinary Biologics Establishment License by the Deputy Administrator for an interim period, subject to the provisions of § 114.2(b).

(1) The U.S. Veterinary Biologics Establishment License for such purpose shall be restricted to a period not to exceed 4 years; *Provided:* That for good cause and when deemed necessary the Deputy Administrator may authorize the issuance of an Establishment License for an additional limited interim period. The termination date for such license shall be established at the time of issuance.

(2) Prior to the termination date, the licensee may request issuance of an establishment license for an indefinite period by application as provided in § 102.3(a).

(3) Before a U.S. Veterinary Biologics Establishment License will be issued for an indefinite period to an establishment previously issued a U.S. Veterinary Biologics Establishment License for an interim period, the licensee shall demonstrate compliance with provisions of the Act and regulations.

(Approved by the Office of Management and Budget under control number 0579-0013)

[39 FR 37762, Oct. 24, 1974; 39 FR 38364, Nov. 1, 1974, as amended at 41 FR 44359, Oct. 8, 1976; 48 FR 57472, Dec. 30, 1983; 50 FR 50763, Dec. 12, 1985]

§ 102.5 U.S. Veterinary Biological Product License.

(a) Authorization to produce each biological product shall be specified on a U.S. Veterinary Biological Product License, issued by the Deputy Administrator, and supplementary to the U.S. Veterinary Biologics Establishment License named therein.

(b) The U.S. Veterinary Biologics Establishment License Number for the establishment in which the product is packaged and labeled as required by the regulations and from which the product is released for marketing shall appear on the U.S. Veterinary Biological Product License with the true name of the product, the product code number, the date of issuance, and any restrictions designated by the Deputy Administrator under paragraph (e) of this section. When necessary to comply with paragraph (e)(2) of this section, the termination date shall also appear on the product license.

(c) The U.S. Veterinary Biological Product License shall be in the following form:

U.S. VETERINARY BIOLOGICAL PRODUCT LICENSE

Washington, D.C., ———.

This is to certify that, pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogus products intended for use in the treatment of domestic animals, the person holding U.S. Veterinary Biologics Establishment License No. —— is authorized to prepare ———— in the facilities designated in the establishment license. Preparation shall be in accordance with the provisions of the Act, the regulations made thereunder, and additional restrictions or requirements when listed below.

This license is subject to termination as provided in the regulations made under the authority contained in said act, and to suspension or revocation if the licensee violates or fails to comply with said act or the regulations made thereunder.

____

Deputy Administrator, Veterinary Services, Animal and Plant Health Service.

(d) The following provisions shall apply to all licensed biological products:

(1) Licensed biological products shall be prepared as required by the regulations and in accordance with a filed Outline of Production as prescribed in §§ 114.8 and 114.9 of this subchapter. No change shall be made in the preparation of a biological product without prior approval of the Deputy Administrator.

(2) The licensee shall distribute the product in any State or other jurisdiction only in accordance with the requirements of such State or other jurisdiction.

(3) When requested by the Deputy Administrator, a licensee shall submit a list of licensed biological products prepared in the licensed establishment.

(e) When the Deputy Administrator determines that the nature of a product necessitates the restriction of its use for the protection of domestic animals, or the public health, interest, or safety, or both, the product shall be subject to such additional restrictions as are prescribed on the license. Such restrictions may include, but not be limited to, those provided in this paragraph.

(1) The biological product may be restricted for use by veterinarians, or under the supervision of veterinarians, or both.

(2) Subject to the conditions in paragraphs (e)(2) (i) and (ii) of this section, production of a licensed biological product may be restricted to a predetermined time period, in which case, the termination date for the license shall be established at the time of issuance.

(i) Immediately prior to the termination date, the licensee may request reissuance of the license. At that time, the licensee shall be given an opportunity to substantiate such request with all available data and information obtained since the license was issued.

(ii) After reviewing the matter with the licensee and considering all data and information obtained from any source, the Deputy Administrator shall either reissue the product license or allow it to terminate.

(Approved by the Office of Management and Budget under control number 0579-0013)

[39 FR 37763, Oct. 24, 1974, as amended at 41 FR 44359, Oct. 8, 1976; 48 FR 57472, Dec. 30, 1983; 50 FR 50764, Dec. 12, 1985]

PART 103—EXPERIMENTAL PRODUCTION, DISTRIBUTION, AND EVALUATION OF BIOLOGICAL PRODUCTS PRIOR TO LICENSING

Sec.

103.1 Preparation of experimental biological products.
103.2 Disposition of animals administered experimental biological products or live organisms.
103.3 Distribution of experimental biological products.

AUTHORITY: 37 Stat. 832-833; 21 U.S.C. 151-158.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

§ 103.1 Preparation of experimental biological products.

Except as otherwise provided in this section, experimental biological products which are neither composed of nor prepared with organisms or antigens used in biologicals already licensed, shall not be prepared in the production facilities of a licensed establishment. Upon application therefor, the Deputy Administrator may authorize the preparation of experimental products on the premises of a licensed establishment if he determines that such preparation will not result in contamination of the licensed products. Each request for permission to prepare an experimental biological product on licensed premises shall indicate the nature of the unlicensed product, designate facilities to be used, and specify precautions which will be taken to prevent contamination of licensed products. Such requests shall be submitted to the Deputy Administrator. Research facilities that are entirely separate and apart from facilities used for the preparation of licensed biological products will not be considered a part of the licensed premises for purposes of this section.

(Approved by the Office of Management and Budget under control number 0579-0013)

[30 FR 11848, Sept. 16, 1965, as amended at 48 FR 57473, Dec. 30, 1983]

§ 103.2 Disposition of animals administered experimental biological products or live organisms.

Safeguards as herein provided shall be established by the research investigator or research sponsor to control disposition of all animals administered experimental biological products or live organisms.

(a) Surviving test animals (including challenged control animals) shall not be removed from the premises on which the tests are conducted for at least 14 days after administration of an experimental biological product or live organisms: *Provided, however,* That this holding period may be increased or decreased as permitted or requested by the Deputy Administrator following review of all relevant information or data available.

(b) All animals administered experimental biological products which are to be slaughtered at establishments subject to the Federal Meat Inspection Act, as amended and extended (21

U.S.C. 601 et. seq.) are subject to the applicable requirements of § 309.16 of this title (Meat Inspection Regulations).

(c) Except as otherwise provided in this paragraph, the research investigator or research sponsor shall maintain adequate records relative to the disposition of each animal administered experimental biological products. These records shall be maintained for a minimum period of two years from the date that an experimental product was administered to such animal, and shall show the name and address of the owner; number, species, class and location of the animals; and if sold, the name and address of the consignee, buyer, commission, firm or abattoir: *Provided, however,* That a research investigator or research sponsor may be exempted from these recordkeeping requirements by the Deputy Administrator on the basis of acceptable data demonstrating that use of the experimental biological product will not result in the presence of any unwholesome condition in the edible parts of animals subsequently presented for slaughter.

(Approved by the Office of Management and Budget under control number 0579-0059)

(44 U.S.C. 3506)

[30 FR 11848, Sept. 16, 1965, as amended at 48 FR 57473, Dec. 30, 1983]

§ 103.3 Distribution of experimental biological products.

Except as provided in this section, no person shall ship or deliver for shipment from one State or Territory or the District of Columbia to any other State or Territory or the District of Columbia any unlicensed biological product for experimental treatment of domestic animals. For the convenience of license applicants and to permit and encourage important research projects, a person may be authorized by the Deputy Administrator to ship unlicensed biological products from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia, for the purpose of evaluating experimental products by treating limited numbers of domestic animals, if the Deputy Administrator determines that the conditions under which the experiment is to be conducted are adequate to prevent spread of disease and approves the procedures set forth in the request for such authorization. Requests for authorization to ship unlicensed biological products for experimental field studies shall be accompanied by the following:

(a) One copy of permit or letter of permission from the proper State authorities of each State involved;

(b) Two copies of a tentative list of the names of the proposed recipients and quantity of experimental product that is to be shipped to each individual. In the event of subsequent changes, additional information shall be furnished when such facts are known;

(c) Two copies of a description of the product, recommendations for use, and results of preliminary research work;

(d) Three copies of labels or label sketches which show the name or identification of the product and bear a statement, "Notice! For Experimental Use Only—Not For Sale," or equivalent. The U.S. Veterinary License legend shall not appear on such labels; and

(e) Two copies of a proposed general plan covering the methods and procedures for evaluating the product and for maintaining records of the quantities of experimental product prepared, shipped and used. At the conclusion of field studies, results shall be obtained, summarized, and submitted to the Veterinary Services.

(f) Data acceptable to the Deputy Administrator demonstrating that use of the experimental biological product in meat animals is not likely to result in the presence of any unwholesome condition in the edible parts of animals subsequently presented for slaughter.

(g) A statement from the research investigator or research sponsor agreeing to furnish, upon the Deputy Administrator's request, additional information concerning each group of meat animals involved prior to movement of these animals from the premises where the test is to be conducted. Such information shall include the owner's name and address; number, species, class and location of animals involved; date shipment is anticipated; along with name and address of consignee, buyer, commission firm or abattoir.

[26 FR 7726, Aug. 18, 1961, as amended at 30 FR 11848, Sept. 16, 1965]

PART 104—PERMITS FOR BIOLOGICAL PRODUCTS

Sec.
104.1 Permit required.
104.2 Permit authorized.
104.3 Permit application.
104.4 Products for research and evaluation.
104.5 Products for distribution and sale.
104.6 Products for transit shipment only.
104.7 Product permit.
104.8 Illegal shipments.

AUTHORITY: 37 Stat. 832-833 (21 U.S.C. 151-158).

SOURCE: 38 FR 32916, Nov. 29, 1973, unless otherwise noted.

§ 104.1 Permit required.

Unless otherwise authorized or directed by the Deputy Administrator, each permit to import a biological product into the United States shall be issued in accordance with the regulations in this part.

(a) No biological product shall be brought into the United States unless a permit has been issued for such product. A separate U.S. Veterinary Biological Product Permit shall be required for each shipment of biological product to be imported: *Provided*, That, a permit shall also be required for each transit shipment of biological products moved through the United States.

(b) Each person importing biological products shall hold an unexpired, unsuspended, and unrevoked permit issued by Veterinary Services. Such person shall reside within the United States, or operate a business establishment within the United States, or both.

§ 104.2 Permit authorized.

(a) Veterinary Services is authorized to issue three types of permits for importing biological products. They shall be:

(1) U.S. Veterinary Biological Product Permit for Research and Evaluation;

(2) U.S. Veterinary Biological Product Permit for Distribution and Sale; or

(3) U.S. Veterinary Biological Product Permit for Transit Shipment Only.

(b) A permit shall not be issued for a biological product from countries known to have exotic diseases, including but not limited to foot-and-mouth disease, rinderpest, fowl pest (fowl plague), swine vesicular disease, Newcastle disease, and African swine fever, if in the opinion of the Deputy Administrator, such products may endanger the livestock or poultry of this country.

(c) A permit shall not be issued until an inspector has determined the condition of the equipment and facilities of the producer, of the applicant, or of both if such a determination is considered necessary by the Deputy Administrator.

(d) A permit shall not be issued for a biological product prepared in the United States, exported, and presented for reentry except as provided in § 104.4(d).

§ 104.3 Permit application.

(a) Each person desiring to import a biological product shall make written application to Veterinary Services for a permit. Blank forms of application shall be furnished upon request.

(b) The application shall specify the type of permit required, the port of entry at which the product shall be cleared through Customs, the estimated quantity involved, and the anticipated date on which the importation shall be made.

(Approved by the Office of Management and Budget under control number 0579-0013)

[38 FR 32916, Nov. 29, 1973, as amended at 48 FR 57473, Dec. 30, 1983]

§ 104.4 Products for research and evaluation.

(a) An application for a U.S. Veterinary Biological Product Permit to import a biological product for Research and Evaluation shall be accompanied by a brief description of such product, methods of propagating antigens including composition of medium, species of animals or cell cultures involved, degree of inactivation or attenuation, recommendations for use, and the proposed plan of evaluation.

(b) A permit to import a biological product for Research and Evaluation shall not be issued unless scientific capabilities of the investigator are determined to be adequate to safeguard domestic animals and protect public health, interest, or safety from any deleterious effects which might result from such product. Special restrictions shall be specified as part of the permit when such restrictions are deemed necessary or advisable by the Deputy Administrator.

(c) A biological product shall not be imported for Research and Evaluation which is not packaged and labeled in accordance with § 112.9 of this subchapter.

(d) When a licensed product has been exported from the United States, a permit may be issued to the producer for a small quantity of such product for in vitro Research and Evaluation tests: *Provided*, That, the importation of such product will not endanger the livestock or poultry of this country.

(Approved by the Office of Management and Budget under control number 0579-0013)

[38 FR 32916, Nov. 29, 1973, as amended at 48 FR 57473, Dec. 30, 1983]

§ 104.5 Products for distribution and sale.

An application for a U.S. Veterinary Biological Product Permit to import a biological product for Distribution and Sale shall be accompanied by supporting material necessary to satisfy the requirements provided in this section.

(a) A permit shall not be issued unless the conditions under which the biological product is to be prepared or the methods to be used are such as to reasonably insure that the product is pure, safe, potent, and efficacious.

(1) Three copies of blueprints of the producing foreign establishment shall be submitted with the application unless satisfactory plans are on file with Veterinary Services from a previous application. The production facilities to be used for each product prepared at the establishment shall be designated.

(2) The manufacturer shall submit written authorization for properly accredited inspectors to inspect without previous notification, and at such times as may be demanded by the aforesaid inspectors, all parts of the establishment in which biological products shall be prepared, all processes of preparation, and all records relative to such preparation.

(3) The manufacturer shall furnish written assurance that a biological product to be imported for Distribution and Sale shall be prepared under the supervision of a person competent by education and experience to handle all matters pertaining to the preparation of such product and that each biological product shall be prepared in accordance with the regulations applicable to the product or in a manner acceptable to the Deputy Administrator so as to carry out the purposes of the Act.

(4) The methods to be used in the preparation of each biological product shall be written into an approved Outline of Production prepared in accordance with the applicable provisions of Part 114 of this subchapter. Four copies of such Outlines of Production shall be submitted to Veterinary Services and be approved before the permit is issued.

(5) Data shall be furnished by the applicant which establishes that the product involved complies with the provisions of the Act and the regulations issued pursuant thereto. When deemed necessary to obtain required information, Veterinary Services may require that the product be tested under field conditions within or outside the United States as the occasion demands.

(b) The permittee shall furnish the following:

(1) Adequate facilities for storing all imported biological products. An inspection of such facilities shall be made by inspectors before a permit is issued and additional inspections shall be made at any time subsequent to the importation of the biological products if deemed necessary by the Deputy Administrator;

(2) Information regarding all claims to be made on labels and advertising matter used in connection with or related to the biological product to be imported;

(3) Mounted copies of final container labels, carton labels, and enclosures to be used with the imported product as provided in Part 112 of this subchapter; and

(4) Samples of each serial from each shipment of biological products imported or offered for importation. Such samples shall be collected, examined, and tested in a manner specified by the Deputy Administrator. The biological products being sampled shall not be further distributed by the permittee until released by Veterinary Services.

(Approved by the Office of Management and Budget under control number 0579-0013)

[38 FR 32916, Nov. 29, 1973, as amended at 48 FR 57473, Dec. 30, 1983; 49 FR 21044, May 18, 1984]

§ 104.6 Products for transit shipment only.

An application for a permit for Transit Shipment Only shall be required when a biological product is being shipped from one foreign country to another foreign country by way of the United States. The shipment shall move under a permit subject to the following restrictions:

(a) The shipment shall be confined to the carrier at all times when such shipment is to transit the United States on the same carrier on which it arrived. If the shipment is to be transferred to a carrier other than the one on which it shall arrive into the United States, a schedule of arrival and departure of each shipment shall be furnished by the permittee to Veterinary Services prior to arrival in the United States.

(b) The permittee shall be responsible to Veterinary Services for handling, storing, and forwarding of the biological product. Veterinary Services shall be notified of all shipments received and forwarded by the permittee and an accurate accounting shall be made.

(Approved by the Office of Management and Budget under control number 0579-0013)

[38 FR 32916, Nov. 29, 1973, as amended at 48 FR 57473, Dec. 30, 1983]

§ 104.7 Product permit.

(a) A permit shall be numbered, shall be dated, and shall be in the following form:

U.S. VETERINARY BIOLOGICAL PRODUCT PERMIT

No. ———

RESEARCH AND EVALUATION OR DISTRIBUTION AND SALE

OR

TRANSIT SHIPMENT ONLY

(Insert One)

Issued at Washington, D.C. on ———

Expires: ———

This permit is issued pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of veterinary biological products. So far as the jurisdiction of the U.S. Department of Agriculture is concerned, ——— is authorized to import ———, prepared by ———, into the United States through the port of ———.

Importation shall be made subject to the following special conditions:

This permit may be revoked if the permittee violates or fails to comply with said Act, the regulations made thereunder, or the conditions specified herein.

———

Veterinary Services, Animal and Plant Health Inspection Service.

(b) The purpose for which the product is imported shall be specified on the permit as for Research and Evaluation, Distribution and Sale, or Transit Shipment Only.

(c) A permit shall not be used after the date specified.

§ 104.8 Illegal shipments.

(a) Biological products which are presented for importation without a permit having been issued shall be returned to the country of origin at the expense of the importer or in lieu thereof, destroyed by Department personnel.

(b) Biological products for Distribution and Sale presented for importation under a permit and found to be worthless, contaminated, dangerous, or harmful shall, within a period of 30 days after such finding, be returned to the country of origin at the expense of the importer or in lieu thereof, destroyed by Department personnel: *Provided*, That such product shall not be returned to the country of origin while bearing a U.S. permit number on the label.

PART 105—SUSPENSION OF BIOLOGICS LICENSES OR PERMITS

Sec.

105.1 Suspension or revocation.
105.2 Notification of infractions.
105.3 Notices re: worthless, contaminated, dangerous, or harmful biological products.
105.4 Termination of licenses for inactivity.

AUTHORITY: 37 Stat. 832-833 (21 U.S.C. 151-158), unless otherwise noted.

§ 105.1 Suspension or revocation.

(a) An establishment license, product license, or permit issued under the Virus-Serum-Toxin Act may be formally suspended or revoked after opportunity for hearing has been accorded the licensee or permittee as provided in Part 123 of this subchapter if the Secretary is satisfied that the license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, shipment, or importation contrary to said Act of any worthless, contaminated, dangerous, or harmful biological product. Such use may be found to exist if:

(1) The construction of the establishment in which the biological product is prepared is defective, or the establishment is not conducted as required by the regulations in Parts 101 through 117 of this subchapter;

(2) The methods of preparation of the product are faulty, or the product contains impurities or lacks potency;

(3) The product is so labeled or advertised as to mislead or deceive the purchaser in any particular;

(4) The licensee or permittee has violated or failed to comply with any provision of the Virus-Serum-Toxin Act or the regulations in Parts 101 through 117 of this subchapter;

(5) The license or permit is otherwise used to facilitate or effect the preparation, sale, barter, exchange, shipment, or importation, contrary to the Virus-Serum-Toxin Act, of any worthless, contaminated, dangerous, or harmful biological product.

(b) In case of willfulness or where the public health, interest, or safety so required the Secretary may, without hearing, informally suspend such establishment license, product license, or permit upon the grounds set forth in paragraph (a) of this section pending determination of formal proceedings under Part 123 of this subchapter for suspension or revocation of the license or permit.

[38 FR 23512, Aug. 31, 1973, as amended at 41 FR 44359, Oct. 8, 1976]

§ 105.2 Notification of infractions.

If an infraction of a requirement of a product license is brought to the attention of the licensee by written notification thereof by Veterinary Services, a subsequent violation of similar nature occurring with the same licensed biological product within 6 months of the said written notification shall be primafacie evidence of willful violation and the license for the product shall be subject to suspension or revocation under the provisions of § 105.1(b).

(21 U.S.C. 151 and 154; 37 FR 28477, 28646; 38 FR 19141)

[42 FR 31430, June 21, 1977]

§ 105.3 Notices re: worthless, contaminated, dangerous, or harmful biological products.

(a) If at any time it appears that the preparation, sale, barter, exchange, shipment, or importation, as provided in the Virus-Serum-Toxin Act, of any biological product by any person holding a license or permit may be dangerous in the treatment of domestic animals, the Secretary may without hearing notify the licensee or permittee, and pending determination of formal proceedings instituted under Part 123 of this subchapter for suspension or revocation of the license or permit insofar as it authorizes the manufacture or importation of the particular product, no person so notified shall thereafter so prepare, sell, barter, exchange, ship, deliver for shipment, or import such product.

(b) If a serial of biological product is found to be unsatisfactory according to applicable Standard Requirements, the Deputy Administrator may notify the licensee to stop distribution and sale of the serial.

[38 FR 23512, Aug. 31, 1973]

§ 105.4 Termination of licenses for inactivity.

If a licensed biological product has not been prepared by the licensee for a period of 5 years, the Deputy Administrator may require that the licensee show intent to resume production within 6 months or the product license be terminated.

[41 FR 44359, Oct. 8, 1976]

PART 106—EXEMPTION FOR BIOLOGICAL PRODUCTS USED IN DEPARTMENT PROGRAMS OR UNDER DEPARTMENT CONTROL OR SUPERVISION

§ 106.1 Biological products; exemption.

The Deputy Administrator may exempt any biological product from one or more of the requirements of this Subchapter if he determines that such product will be used by the Department or under the supervision or control of the Department in the prevention, control or eradication of animal diseases in connection with (a) an official USDA program; or (b) an emergency animal disease situation, or (c) a USDA experimental use of the product.

(37 Stat. 832-833; 21 U.S.C. 151-158)

[45 FR 65184, Oct. 2, 1980]

PART 108—FACILITY REQUIREMENTS FOR LICENSED ESTABLISHMENTS

Sec.
108.1 Applicability.
108.2 Plot plans, blueprints, and legends required.
108.3 Preparation of plot plans.
108.4 Preparation of blueprints.
108.5 Preparation of legends.
108.6 Revision of plot plans, blueprints, and legends.
108.7 Filing of plot plans, blueprints, and legends.
108.8 Construction of buildings.
108.9 Dressing rooms and other facilities.
108.10 Outer premises and stables.
108.11 Water quality requirements.

AUTHORITY: 21 U.S.C. 151-158; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 39 FR 16854, May 10, 1974, unless otherwise noted.

§ 108.1 Applicability.

Unless otherwise authorized by the Deputy Administrator, all buildings, appurtenances, and equipment used in the preparation of biological products shall be in compliance with the regulations in this part. Each land area on which such buildings and appurtenances are located shall be identified by an address which shall appear on the establishment license.

§ 108.2 Plot plans, blueprints, and legends required.

Each applicant for an establishment license shall prepare a plot plan showing all buildings for each particular land area, blueprints for each building used in the preparation of biological products and legends containing a brief description of all activities in each room or area.

§ 108.3 Preparation of plot plans.

Plot plans shall show all of the buildings on a particular land area, whether or not they are all used for the preparation and initial shipping of biological products: *Provided*, That, when a great number of buildings are on the same premises, only those surrounding the buildings used for preparation and initial shipping of biological products shall be shown. The presence of the remainder of the buildings may be accounted for by a single statement denoting the total number of such buildings not used for the preparation or shipping of biological products.

(a) Reduce the entire premises to any standard scale on one sheet of paper which meets any of the American standard trimmed sizes. Indicate the scale used.

(b) Clearly mark the boundaries of the licensed premises and indicate what marking denotes the boundaries. Such boundaries shall coincide with some readily apparent perimeter line. Identify all fences, walls, or streets.

(c) Show buildings as reduced dimensional drawings in the proper scale distance relationship with each other.

(d) Number, letter, or otherwise identify all buildings so that they may be correlated with the respective blueprints and legends.

(e) Describe on the plot plan the use of immediate adjacent properties such as, residential area, pasture, box factory, or the like.

(f) Show compass points.

(g) Show date of preparation.

(h) Apply signature of responsible official of the firm.

§ 108.4 Preparation of blueprints.

(a) Blueprints, drawn to any suitable scale, on regular blueprint paper or a good grade of white paper of any one of the American standard trimmed sizes shall be acceptable: *Provided*, That the same scale shall be used for future revisions unless the entire blueprint is revised. Indicate the scale used.

(b) Use a single sheet of paper for each floor of all buildings in which biological products are prepared. Illustrate in detail the areas in each building utilized for such preparation.

(c) If only a portion of a floor is used in the preparation of a biological product, the blueprint shall illustrate the entire floor in essentially the same detail throughout. All functions or activities performed in the remainder of the floor shall be indicated.

(d) Identify the floors if the drawing is not for all floors in a multiple-story building and identify activities on each floor.

(e) Identify all rooms by letters or numbers.

(f) Show the location of important stationary equipment by a suitable code which will be further identified on legends.

(g) Explain on the blueprint or on the legend, by a statement or listing, which rooms are equipped with water outlets, drains, and lighting. Show the location of doors and windows.

(h) Show compass points.

(i) Show building number.

(j) Show date of preparation.

(k) Apply signature of responsible official of firm.

§ 108.5 Preparation of legends.

A brief description of the activities performed in each room or area shall be prepared as provided in this section and shall be referred to as a legend. Legends shall be provided for each plot plan and each blueprint or drawing. All pages of the legends shall be numbered, identified with corresponding plot plan or blueprint, and submitted in booklet form either stapled together or clipped into a suitable folder.

(a) Plot plan legends shall show the following:

(1) Number of each building and the functions performed in each: *Provided*, That if it is a multiple-story building in which biological products are prepared or handled, briefly describe functions performed on each floor.

(2) A practical and nontechnical description of construction materials used throughout those buildings used entirely or partially for production and handling of biological products.

(b) Blueprint legends shall show the following:

(1) A listing of all rooms by identifying letters or numbers and the fractions prepared in each. Exceptions may be listed for general purpose areas or rooms. Functions performed in each area and room shall be described, whether the licensed or unlicensed products. In rooms where products are exposed to the surroundings, a description of decontamination procedures and other precautions against cross contamination shall be included.

(2) A listing of the coded stationary equipment.

(3) A general listing of other essential biological equipment such as mills, centrifuges, mixing tanks, bottling and sealing equipment, and the like, which are not regarded as stationary but are maintained in certain rooms.

[39 FR 16854, May 10, 1974, as amended at 40 FR 51413, Nov. 5, 1975; 50 FR 50764, Dec. 12, 1985]

§ 108.6 Revision of plot plans, blueprints, and legends.

Preliminary drawings may be submitted to Veterinary Services for comment prior to construction of new facilities or when remodeling is anticipated, old facilities are to be torn down, or other changes affecting the workflow are to be made. The licensee shall:

(a) Prepare revised plot plans, blueprints, or legends and submit to Veterinary Services for review and filing when changes have been completed. Also prepare a statement to accompany each revision to identify, by date of the superseded item, what is being superseded.

(b) Prepare a drawing of the revised rooms, unit, or section to the same scale as the blueprint on file which shall be stamped and applied to the existing blueprint. If changes are numerous, prepare a new blueprint.

(c) Drawings of new buildings may be added to existing plot plans. Indicate the distance from surrounding buildings and boundary lines.

(d) Any change prescribed in this section shall necessitate a change in one or more pages of the respective legends. The revised pages shall carry the same numbers as superseded pages.

§ 108.7 Filing of plot plans, blueprints, and legends.

Three copies of all plot plans, blueprints, and legends, including revisions, shall be submitted to Veterinary Services for review and filing. When the reviewer takes exception to a submitted item, such item shall be returned with appropriate comments for correction and resubmission. Acceptable submissions shall be stamped as filed and the date noted. One stamped copy shall be returned and two copies retained for Veterinary Services files.

§ 108.8 Construction of buildings.

(a) The floors, walls, ceilings, partitions, posts, doors, and all other parts of all structures, rooms, or facilities used for the preparation of biological products or ingredients of biological products at licensed establishments shall be of such material, construction, and finish as may be readily and thoroughly cleaned.

(b) All rooms used in connection with the preparation of biological products shall be so constructed and arranged as to prevent cross-contamination of such biological products. Halls or walkways shall be provided for the movement of personnel or materials to each biological products preparation area without going through another such area.

(c) Rooms or compartments separate from the remainder of the establishment shall be provided at licensed establishments for preparing, handling, and storing virulent or dangerous microorganisms and products.

(d) All rooms and compartments at licensed establishments shall have an adequate air handling system to supply proper ventilation sufficient to insure sanitary and hygenic conditions for the protection of the products and personnel.

(e) The supply of hot and cold water at licensed establishments shall be ample and clean. Adequate facilities shall be provided for the distribution of water in each establishment and for the washing of all containers, machinery, instruments, other equipment, and animals used in the preparation of a biological product.

(f) There shall be an efficient drainage and plumbing system for each licensed establishment and premises thereof, and all drains and gutters shall be properly installed with approved traps and vents.

§ 108.9 Dressing rooms and other facilities.

Each licensed establishment shall have dressing rooms, toilet facilities, and lavatory accommodations, including hot and cold running water, soap, towels, and the like. They shall be in sufficient number, ample in size, conveniently located, properly ventilated, and meeting all requirements as to sanitary construction and equipment.

(a) These rooms and facilities shall be separate from rooms or compartments in which biological products are prepared, handled, or stored.

(b) These rooms and facilities shall be so located in the establishment as to be readily accessible to all persons without having to enter or pass through biological products preparation areas.

§ 108.10 Outer premises and stables.

(a) The outer premises of licensed establishments, embracing docks, driveways, approaches, yards, pens, chutes, and alleys shall be drained properly and kept in a clean and orderly condition. No nuisance shall be allowed in any licensed establishment or on its premises.

(b) Stables or other premises for animals used in the production or testing of biological products at licensed establishments shall be properly ventilated and lighted, appropriately drained and guttered, and kept in sanitary condition.

(c) Every practical precaution shall be taken to keep licensed establishments free of flies, rats, mice, and other vermin. The accumulation, on the premises of an establishment, of any material in which flies or other vermin may breed is forbidden. Suitable arrangements, in keeping with the local health practices, shall be made for the disposal of all refuse.

§ 108.11 Water quality requirements.

A certification from the appropriate water pollution control agency, that the establishment is in compliance with applicable water quality control standards, pursuant to section 401 of the Federal Water Pollution Control Act, as amended (86 Stat. 877; 33 U.S.C. 1341), shall be filed with Veterinary Services for each licensed establishment.

PART 109—STERILIZATION AND PASTEURIZATION AT LICENSED ESTABLISHMENTS

Sec.
109.1 Equipment and the like.
109.2 Sterilizers.
109.3 Pasteurizers.

AUTHORITY: 37 Stat. 832-833; 21 U.S.C. 151-158.

§ 109.1 Equipment and the like.

(a) All containers, instruments, and other apparatus and equipment, before being used in preparing, handling, or storing biological products, at a licensed establishment, except as otherwise prescribed herein, shall be thoroughly sterilized by live steam at a temperature of at least 120° C. for not less than one-half hour, or by dry heat at a temperature of at least 160° C. for not less than one hour. If for any reason such methods of sterilization are impracticable, then a process known to be equally efficacious in destroying microorganisms and their spores may be substituted after approval by the Deputy Administrator.

(b) Instruments which are found to be damaged by exposure to the degree of heat prescribed in this section, after having been thoroughly cleaned, may be sterilized by boiling for not less than 15 minutes.

[23 FR 10051, Dec. 23, 1958, as amended at 34 FR 18119, Nov. 11, 1969]

§ 109.2 Sterilizers.

Steam and dry-heat sterilizers used in connection with the processing of biological products at licensed establishments shall be equipped with automatic temperature recording gauges: *Provided*, That other record keeping systems may be used when approved by the Deputy Administrator. When gauges are used, they shall be periodically standardized to assure accuracy. Charts and other temperature records made during production shall be available at all times charts and records shall be kept in accordance with Part 116 of this chapter.

[35 FR 16039, Oct. 13, 1970]

§ 109.3 Pasteurizers.

All pasteurizing equipment shall meet the requirements in paragraphs (a), (b), and (c) of this section and be acceptable to Veterinary Services.

(a) Metal serum containers shall be used in licensed establishments. During the heating process, each container shall be surrounded by a separate water jacket or equivalent so that the entire container, including its lid, is heated to the required temperature. Each serum container shall be equipped with a motor-driven agitator and a separate automatic recording thermometer.

(b) Each water bath shall have an automatic temperature control to limit the temperature of the water to a maximum of 62° C., an automatic recording thermometer, an indicating thermometer set in a fixed position, and circulating mechanism adequate to insure equal temperatures throughout the bath. The heating unit for the bath shall be separated from the serum container and the water jacket.

(c) Accurate thermometers at licensed establishments shall be used at frequent intervals to check temperatures of the serum as registered by recording thermometers.

[35 FR 16039, Oct. 13, 1970]

PART 112—PACKAGING AND LABELING

Sec.

112.1 Applicability.
112.2 Final container label, carton label, and enclosure.
112.3 Diluent labels.
112.4 Subsidiaries, divisions, distributors, and permittees.
112.5 Review and approval of labeling.
112.6 Packaging biological products.
112.7 Special additional requirements.
112.8 For export only.
112.9 Biological products imported for research and evaluation.
112.10 Special packaging and labeling.

AUTHORITY: 21 U.S.C. 151-158; 37 FR 28477, 28646; 38 FR 19141.

SOURCE: 38 FR 12094, May 9, 1973, unless otherwise noted.

§ 112.1 Applicability.

Unless otherwise authorized or directed by the Deputy Administrator, each biological product prepared at a licensed establishment or imported shall be packaged and labeled as prescribed in this part before it is removed from the licensed establishment or presented for importation: *Provided*, That biological products to be imported for research and evaluation shall be subject to packaging and labeling requirements as may be issued pursuant to § 112.9.

(a) No person shall apply or affix, or cause to be applied or affixed, any label, stamp, or mark, to any carton or final container of a biological product prepared or received in a licensed establishment or imported that is false or misleading in any particular or is not in compliance with the regulations.

(b) No person shall alter, mark, or remove any label or mark on any carton or final container of a biological product so as to falsify the label or make it misleading.

(c) Labels stamped, printed, or glued directly on cartons and final containers, shall be legible throughout the dating period. Biological products shall be withheld from the market if such labels have been altered, mutilated, destroyed, obliterated, or removed.

§ 112.2 Final container label, carton label, and enclosure.

(a) Unless otherwise provided, final container labels, carton labels, and enclosures (inserts, circulars, or leaflets) shall include the information specified in this section.

(1) The principal part of the true name of the biological product which name shall be identical with that shown in the product license under which such product is prepared, or the permit under which it is imported, shall be prominently lettered and placed giving equal emphasis to each word composing it. Descriptive terms used in the true name on the product license or permit shall also appear. Abbreviations of the descriptive terms may be used on the final container label if complete descriptive terms appear on a carton label and enclosures;

(2) If the biological product is prepared in the United States, the name and address of the producer (licensee or subsidiary) or if the biological product is prepared in a foreign country, the name and address of the permittee and of the foreign producer.

(3) The license or permit number assigned by the Department which shall be shown only in one of the following forms respectively: "U.S. Veterinary License No. ——," or "U.S. Vet. License No. ——," or "U.S. Vet Lic. No. ——," or "U.S. Veterinary Permit No. ——," or "U.S. Permit No. ——."

(4) Storage temperature recommendation for the biological product stated as not over 45° F. or stated as not over 7° C. or stated as not over 45° F. or 7° C.

(5) Full instructions for the proper use of the product, including vaccination schedules, warnings, cautions, and the like: *Provided*, That in the case of very small final container labels or carton, a statement as to where such information is to be found, such as "See enclosure for complete directions," "Full directions on carton," or comparable statement;

(6) In the case of a multiple-dose final container, a warning to use entire contents when first opened: *Provided*, That a diagnostic or a desensitizing antigen packaged in a multiple-dose final container is exempt;

(7) If the biological product contains viable or dangerous organisms or viruses, a warning to "Burn this container and all unused contents," except that in the case of a small one-dose container, the statement "Burn this container" or "Burn this vial" may be used.

(8) In the case of a biological product recommended for use in domestic animals, the edible portion of which may be used for food purposes, a withholding statement of not less than 21 days to read: "Do not vaccinate within (insert number) days before slaughter" or "Do not vaccinate food-producing animals within (insert number) days before slaughter": *Provided*, That longer periods shall be stated when deemed necessary by the Deputy Administrator. Very small final container labels are exempted from this requirement.

(9) The following information shall appear on the final container label and carton label, if any, but need not appear on the enclosure:

(i) A permitted expiration date;

(ii) The number of doses where applicable;

(iii) The recoverable quantity of the content of each final container stated in cubic centimeters (cc.) or milliliters (ml.) or units.

(iv) A serial number by which the product can be identified with the manufacturer's records of preparation: *Provided*, That when a liquid antigenic fraction is to be used instead of a water diluent for one or more desiccated antigenic fractions in a combination package, a hyphenated serial number composed of a serial number for the desiccated fraction and the serial number for the liquid fraction shall be used on the carton;

(10) In the case of a product which contains an antibiotic added during the production process, the statement "Contains —— as a preservative," or an equivalent statement indicating the antibiotic added shall appear on cartons and enclosures if used: *Provided*, That if cartons are not used, such information shall appear on the final container label;

(11) The number of final containers of biological product and the number of doses in each final container shall be stated on each carton label for all cartons containing more than one final container of biological product. The number of final containers of diluent, if any, and the quantity in each shall also be stated on each carton label.

(b) Labels may also include any other statement which is not false or misleading and may include factual statements regarding variable response of different animals when vaccinated as directed but may not include disclaimers of merchantability, fitness for the purpose offered, or responsibility for the product.

(c) Labels of biological products prepared at licensed establishments or imported shall not include any statement, design, or device, which overshadows the true name of the product as licensed or which is false or misleading in any particular or which may otherwise deceive the purchaser.

(d) Carton labels and enclosures shall be subject to paragraph (d)(1), (d)(2), and (d)(3) of this section.

(1) The statement, "Restricted to use by or under the direction of a veterinarian" or "Restricted to use by a veterinarian," shall be used on all carton labels and enclosures when such restriction is prescribed on the product license.

(2) If the licensee states on the carton labels and enclosures of a product that its sales are restricted to veterinarians, then the entire production of that particular product in the licensed establishment shall be so restricted by the licensee.

(3) The statement "For veterinary use only" or an equivalent statement

may appear on the carton labels and enclosures for a product if such statement is being used to indicate that the product is recommended specifically for animals, and not for humans.

(e) When label requirements of a foreign country conflict with the requirements as prescribed in this part, special labels may be approved for use on biological products to be exported to such country. When laws, regulations, or other requirements of foreign countries require exporters of biological products prepared in a licensed establishment to furnish official certification that such products have been prepared in accordance with the Virus-Serum-Toxin Act and regulations issued pursuant thereto, such certification may be made by Veterinary Services upon request of the licensee.

(f) If a carton label or an enclosure is required to complete the labeling for a multiple-dose final container of liquid biological product, only one final container shall be packaged in each carton: *Provided*, That if the multiple-dose final container is fully labeled without a carton label or enclosure, two or more final containers may be packaged in a single carton which shall be considered a shipping box. Labels or stickers for shipping boxes shall not contain false or misleading information but need not be submitted for approval.

(Approved by the Office of Management and Budget under control number 0579-0013)

[38 FR 12094, May 9, 1973, as amended at 39 FR 16856, May 10, 1974; 41 FR 44359, Oct. 8, 1976; 42 FR 11825, Mar. 1, 1977; 42 FR 29854, June 10, 1977; 42 FR 41850, Aug. 19, 1977; 48 FR 57473, Dec. 30, 1983]

§ 112.3 Diluent labels.

Each final container of diluent, other than a liquid biological product, packaged with desiccated biological products shall bear a label that includes the following:

(a) The name—Sterile Diluent.

(b) True name of the biological product with which the diluent is packaged, except that when the firm packages all desiccated biological products with the same diluent, or two or more types of diluent are used, and the licensees' methods of identification and storage insure that all products are packaged with the correct type of diluent, labels affixed to the containers of diluent are exempt from this provision.

(c) The recoverable quantity of contents in cubic centimeters (cc) or milliliters (ml).

(d) A serial number by which the diluent can be identified with the manufacturer's records of preparation;

(e) Name and address of the licensee or the permittee;

(f) In the case of a diluent with which a desiccated biological product is to come in contact while the diluent is in its original container; and,

(1) Is in a multiple-dose container, a positive warning that all of the biological product shall be used at the time the container is first opened; and/or

(2) The biological product is composed of viable or dangerous organisms or viruses, the notice, "Burn this container and all unused contents," except that, in the case of a small one-dose container, the statement "Burn this container" or "Burn this vial" may be used.

(g) The establishment license number or the permit number, as the case may be, in one of the forms provided in § 112.2(a)(3).

[38 FR 12094, May 9, 1973; 38 FR 13476, May 22, 1973, and amended at 39 FR 16856, May 10, 1974]

§ 112.4 Subsidiaries, divisions, distributors, and permittees.

Labels used by subsidiaries, divisions, distributors, and permittees shall comply with requirements for review, approval, and filing of labels used for licensed biological products distributed and sold by licensees and as provided in this section.

(a) *Subsidiaries*. Labels to be used on a licensed biological product prepared by a subsidiary operating in a licensed establishment shall be submitted in accordance with § 112.5. Only labels approved for use on such product shall be used by the subsidiary.

(b) *Divisions*. Labels to be used on a licensed biological product prepared in a licensed establishment for distribution by a division or marketing unit of the licensee shall be submitted in accordance with § 112.5.The name, address, and license number of the licensee shall be prominently placed on such labels. The relationship of the division or marketing unit to the licensee shall appear prominently on the label by use of the term "division of" or equivalent.

(c) *Distributors.* The name and address of the distributor or any statement, design, or device shall not be placed on the labels or containers of a licensed biological product in a manner which could be false or misleading or which could indicate that the distributor is the manufacturer of such product or operating under the license number shown on the label. The manufacturer shall be identified by name, address, and license number with the term "manufactured by," "produced by," or an equivalent term prominently placed in connection therewith. The name and address of the distributor may be placed on labels or containers if the term "distributor," or "distributed by," or an equivalent term is prominently placed in connection therewith.

(d) *Permittees.* The name and address of the permittee and any statement, design, or device shall not be placed on the labels or containers of a biological product imported for sale and distribution in accordance with § 104.5 in a manner which could be false or misleading or which could falsely indicate that the permittee is the manufacturer of such product. The manufacturer shall be identified by name and address with the term "manufactured by," "produced by," or an equivalent term prominently placed in connection therewith. Reference to the permittee shall be made by name, address, and permit number with the term "imported by," "produced for," or an equivalent term prominently placed in connection therewith.

[50 FR 46417, Nov. 8, 1985]

§ 112.5 Review and approval of labeling.

Labels used with biological products prepared at licensed establishments or imported for general distribution and sale shall be reviewed for compliance with the regulations and approved in writing by Veterinary Services prior to use.

(a) Transmittal forms, furnished by Veterinary Services upon request, shall be used with each submission of sketches (including proofs) and labels. Separate forms shall be used for each biological product but only one copy of the form shall be used for all sketches and labels submitted at the same time for the same biological product.

(b) Sketches may be submitted for comment to Veterinary Services by the licensee or permittee before preparing the finished label. Such sketches shall be returned to the licensee or permittee with comments, if any. Failure of the reviewer to take exception to a sketch shall not constitute approval of a finished label subsequently prepared.

(c) All labels shall be submitted to Veterinary Services for review and written approval. Only labels which are approved shall be used. When changes are made in approved labels, the new labels shall be subject to review and approval before use.

(d) Labels and sketches submitted shall be prepared in the number and manner prescribed in this paragraph.

(1) Copies required:

(i) Two copies of each sketch shall be submitted. One copy shall be returned with applicable comments. One copy shall be held on file by Veterinary Services until replaced by a finished label but not for more than 1 year after processing: *Provided,* That sketches submitted in support of a license or permit shall be held as long as the application is considered active.

(ii) At least three copies of a label shall be submitted: *Provided,* That, when an enclosure is to be used with more than one biological product, one extra copy shall be required for each additional product. Two copies of each label will be retained by Veterinary Services. All remaining copies shall be stamped and returned. Labels to which exceptions are taken shall be marked as sketches and handled according to § 112.5(d)(1)(i).

(2) Mounting:

(i) Each label or sketch shall be securely fastened to a separate sheet of heavy bond paper (8½" × 11") in such a manner that all information is available for review.

(ii) Two-or-three part cartons, including "sleeves," shall be considered as one label. All parts shall be submitted together.

(iii) (*a*) When two final containers are packaged together in a combination package, the labels for each shall be mounted on the same sheet of paper and shall be treated as one label.

(*b*) If either final container label is also used alone or in another combination package, sets of separate labels for each biological product with which it is used shall be submitted for review.

(iv) When the same final container label is applied by different methods such as paper or screen printing, one of each shall be mounted on the same sheet of paper as one submission.

(3) To appear on the top of each page:

(i)(*a*) Name and product code number of the biological product as it appears on the product license or permit.

(*b*) Extra copies of enclosures to be used with another product shall bear the name and code number of the product affected.

(ii) (*a*) Designation of the specimen, as a sketch, final container label, carton label, or enclosure.

(*b*) If two final container labels or multiple parts are on one sheet, each shall be named, and the label or part being revised shall be designated.

(iii) Size of package (doses, ml., cc., or units) for which the labels or enclosures are to be used.

(4) To appear on the bottom of each page: The reason for the submission shall be stated in the lower left hand corner as:

(i) To replace Label and/or Sketch No. ———;

(ii) Addition to Label No. ———;

(iii) Refer to Label No. ———;

(iv) License Application Pending ———;

(v) Foreign Language Copy of Label No. ———.

A 2-inch space shall be reserved in the lower right hand corner. A label number shall be assigned by Veterinary Services to each sketch and label reviewed. It shall be stamped in the space reserved and shall be used for reference to such label or sketch in all subsequent correspondence.

(e) Special requirements for foreign language labels:

(1) If true, a statement that the label is a direct translation from a corresponding approved domestic label.

(2) If the foreign language label is not a direct translation of an approved domestic label, an English version shall be submitted with an explanation for the difference in texts.

(3) Foreign language portion of a bilingual label shall be a true translation of the English portion. Reference to additional information on the enclosure shall not be made unless that enclosure is also bilingual.

(f) When a request is received from Veterinary Services, the licensee or permittee shall submit a list of all approved labels currently being used. Each label listed shall be identified as to:

(1) Name and product code number as it appears on the product license or permit for the product; and

(2) Where applicable, the size of the package (doses, ml., cc., or units) on which the label shall be used; and

(3) Label number and date assigned; and

(4) Name of licensee or subsidiary appearing on the label as the producer.

[38 FR 12094, May 9, 1973, as amended at 48 FR 57473, Dec. 30, 1983; 49 FR 21044, May 18, 1984]

§ 112.6 Packaging biological products.

(a) Each multiple-dose final container of a biological product which requires a diluent for administration shall be packaged in an individual carton with a container of the proper volume of diluent for that dose as specified in the filed Outline of Production. Each multiple-dose final container of a product which does not require a diluent for administration need not be packaged in an individual carton unless the final container labeling does not contain all information required by the regulations. Such information must be included in or on a carton. Exceptions are provided in paragraphs (c) and (d) of this section and § 112.8.

(b) Single-dose final containers of a product need not be packaged one per carton. For single-dose products which require a diluent for administration, the number of containers of the proper amount of diluent specified in the filed Outline of Production for the number of doses contained in the carton shall be included in each carton.

(c) Poultry products for mass administration (including but not limited to administration through drinking water and spray) and products used in automatic vaccinating systems (including but not limited to pneumatic beak injectors and automated needle injectors) may be packaged in multiple-dose final containers as specified in the filed Outline of Production. Poultry products for manual administration to individual birds shall not exceed 1,000 doses in each final container. Diluent need not be packaged with the final container(s) of the product, but the licensee shall provide the required number of containers of diluent as specified in the filed Outline of Production. The following requirements apply to cartons containing more then one final container of poultry product:

(1) They shall be sealed prior to leaving the licensed establishment.

(2) The contents may not be repackaged.

(3) The contents of such cartons may not be sold in fractional units.

(4) The following statement must appear in a prominent place on the carton label: "Federal regulations prohibit the repackaging or sale of the contents of this carton in fractional units. Do not accept if seal is broken."

(d) Diluent for the following products need not be packaged with the final container(s) of the product, but the licensee shall provide the consumer with the required number of containers of the proper amount of diluent as specified in the filed Outline of Production:

(1) Marek's Disease Vaccine.

(2) Poultry vaccines administered to individual birds using automatic vaccinating equipment.

[47 FR 8761, Mar. 2, 1982, as amended at 48 FR 12691, Mar. 28, 1983]

§ 112.7 Special additional requirements.

The label requirements in this section are additional to those prescribed elsewhere in this part.

(a) In the case of biological products containing live Newcastle Disease virus, a caution statement indicating that Newcastle Disease can cause inflammation of the eyelids of humans, and a warning to the user to avoid infecting his eyes shall be included on the enclosure.

(b) In the case of a biological product containing infectious bronchitis virus, all labels shall show the infectious bronchitis virus type or types used in the product. Abbreviation is permitted.

(c) In the case of a biological product containing inactivated rabies virus, carton labels, enclosures, and all but very small final container labels shall include a warning against freezing and the recommendations provided in this paragraph.

(1) That vaccine be administered to animals at 3 months of age or older, with a repeat dose 1 year later.

(2) Subsequent revaccination as determined from the results of duration of immunity studies conducted as prescribed in § 113.129 (b) or (c) or both.

(3) Subsequent revaccination recommendations as determined from the results of the duration from the results of the duration of immunity studies conducted as prescribed in § 113.129 (b) or (c) or both.

(4) The statement "In high risk areas, annual revaccination is recommended": *Provided,* That such statement need not appear if the label already contains a recommendation for annual revaccination.

(d) In the case of a biological product containing modified live rabies virus, the carton labels, enclosures, and all but very small final container labels shall include the recommendations provided in this paragraph.

(1) For low egg-passage (below the 180th egg-passage level) the statement "For Use in Dogs Only! Not For Use in Any Other Animal!"

(2) For other vaccines containing modified live rabies virus, the statement "For Use In (designate

animal(s)) Only! Not For Use In Any Other Animal!"

(3) Intramuscular injection at one site in the thigh shall be recommended.

(4) The statement "In event of accidental exposure to the vaccine virus, the possible hazard to human health should be considered and State Public Health Officials should be consulted for specific recommendations "shall be prominently placed on all carton labels and on enclosures, if used.

(5) That vaccine be administered to animals at 3 months of age or older, with a repeat dose 1 year later.

(6) Subsequent revaccination as determined from the results of the duration of immunity studies conducted as prescribed in § 113.147 (b) or (c) or both.

(e) In the case of bovine rhinotracheitis vaccine containing modified live virus, all labeling except small final container labels shall bear the following statement: "Do not use in pregnant cows or in calves nursing pregnant cows.": *Provided*, That such vaccines which have been shown to be safe for use in pregnant cows may be excepted from this label requirement by the Deputy Administrator.

(f) Unless otherwise authorized in a filed Outline of Production, labels for inactivated bacterial products shall contain an unqualified recommendation for a repeat dose to accomplish primary immunization to be given at an appropriate time interval: *Provided*, That, repeat dose recommendations prescribed in paragraphs (f) (1) through (3) of this section are required for products containing the fractions listed.

(1) *Clostridium haemolyticum*. "Repeat the dose every 5 or 6 months in animals subject to reexposure."

(2) *Erysipelothrix rhusiopathiae*. "Swine: For breeding animals, repeat after 21 days and annually. Turkeys: Repeat dose every 3 months."

(3) *Clostridium botulinum Type C*. "Revaccinate breeders 1 month before breeding."

(g) In the case of autogenous biologics, labels shall include the recommended dose, the number of repeat doses, if any, and the interval recommended between doses; *Provided*, That the label shall not show:

(1) The identity of the herd or flock from which the culture was isolated; or

(2) The name(s) of the person(s) responsible for making the isolations.

(h) In the case of a liquid product authorized in a filed Outline of Production to be used as a diluent in a combination package, the carton labels and enclosures used for serials which are either not tested for bactericidal or viricidal activity or have been found unsatisfactory by such test shall contain the statement: "CAUTION: DO NOT USE AS DILUENT FOR LIVE VACCINES."

(i) In the case of wart vaccine, recommendations shall be limited to use in cattle. Indications for use shall be for prophylactic use only, as an aid in the control of viral papillomas (warts). All labels shall include a dosage recommendation of at least 10 ml to be given subcutaneously and the dose repeated in 3 to 5 weeks.

(j) Unless otherwise authorized in an Outline of Production filed subsequent to the effective date of these amendments, all but very small final container labels for Feline Panleukopenia Vaccines shall contain the following recommendations for use:

(1) *Killed virus vaccines*. Vaccinate healthy cats of any age with one dose except that if the animal is less than 12 weeks of age, a second dose should be given at 12 to 16 weeks of age. Annual revaccination with a single dose is recommended.

(2) *Modified live virus vaccines*. Vaccinate healthy cats of any age with one dose except that if the animal is less than 12 weeks of age, a second dose should be given at 12 to 16 weeks of age. Annual revaccination with a single dose is recommended. Do not vaccinate pregnant cats.

(k) In the case of normal serum, antiserum, or antiserum derivatives, the type of preservative used shall be indicated on all labels.

(l) Unless acceptable data has been filed with Veterinary Services, to show that development of corneal opacity is not associated with the product, carton labels and enclosures used with biological products containing modified live canine hepatitis virus or modified live canine adenovirus Type 2 shall bear the following statement: "Occasionally, transient corneal opacity may occur following the administration of this product."

(m) In the case of a biological product containing modified live canine hepatitis virus or modified live canine adenovirus type 2, the carton label or enclosure shall bear the following statement: "Occasionally transient corneal opacity may occur following the administration of this product.": *Provided,* That, if acceptable data have been filed with Veterinary Services to indicate that the development of corneal opacity is not associated with the use of a product, the following alternate statement shall be used: "Data indicate that the development of corneal opacity is not associated with the use of this product."

[38 FR 12094, May 9, 1973, as amended at 39 FR 16856, May 10, 1974; 40 FR 20066, May 8, 1975; 40 FR 30803, July 23, 1975; 40 FR 31593, July 28, 1975; 40 FR 49295, Oct. 22, 1975; 40 FR 51413, Nov. 5, 1975; 40 FR 53378, Nov. 18, 1975; 42 FR 11825, Mar. 1, 1977; 42 FR 28520, June 3, 1977; 44 FR 71406, Dec. 11, 1979; 48 FR 9506, Mar. 7, 1983; 49 FR 21044, May 18, 1984; 49 FR 22770, June 1, 1984; 50 FR 20089, May 14, 1985]

§ 112.8 For export only.

The applicable regulations for packaging and labeling a biological product produced in the United States shall apply to such biological product if exported from the United States except as otherwise provided in this section. Only labels approved as provided in § 112.5 shall be used.

(a) Biological products which have been packaged and labeled for export or which have been exported, shall be subject to the applicable provisions in this paragraph.

(1) After leaving the licensed establishment, a biological product shall not be bottled, repackaged, relabeled, or otherwise altered in any way while in the United States; and

(2) An exported biological product shall not be returned to the United States: *Provided,* That, in the case of a biological product exported in labeled final containers, the Deputy Administrator may authorize by permit the importation of a limited number for research and evaluation by the producing licensee; and

(3) An exported biological product which is bottled, rebottled, or altered in any way in a foreign country shall not bear a label which indicates by establishment license number that it has been prepared in the United States.

(b) Desiccated and frozen liquid products, packaged and labeled as for domestic use, may be exported without the diluent required for rehydration or dilution, as the case may be, if the labeling includes adequate instructions for preparing the product for use and the words "For Export Only".

(c) Final containers of products, labeled or unlabeled, may be exported in sealed shipping boxes, adequately identified as to contents with an approved label, and plainly marked "For Export Only": *Provided,* That such products shall not be diverted to domestic use.

(d) Completed inactivated liquid products, antiserums, and antitoxins, may be exported in large multiple-dose containers identified with an approved label that contains the words "For Export Only" prominently displayed.

(e) Concentrated inactivated liquid product, completed except for dilution to the proper strength for use, may be exported in large multiple-dose containers identified with an approved label that contains the words "For Export Only" prominently displayed.

[38 FR 12094, May 9, 1973, as amended at 39 FR 19202, May 31, 1974; 40 FR 46093, Oct. 6, 1975; 43 FR 11145, Mar. 17, 1978]

§ 112.9 Biological products imported for research and evaluation.

A biological product imported for research and evaluation under a permit issued in accordance with § 104.4, with the exception of products imported under § 104.4(d), shall be labeled as provided in this section.

(a) The label shall identify the product and the name and address of the manufacturer and shall provide instructions for proper use of the product, including all warnings and cautions needed by the permittee to safely use the product.

(b) Labels on each product to be further distributed in accordance with § 103.3 shall bear the statement "Notice! For Experimental Use Only—Not for Sale!"

(c) The labeling shall contain any other information deemed necessary by the Deputy Administrator and specified on the permit.

[50 FR 46417, Nov. 8, 1985]

§ 112.10 Special packaging and labeling.

A biological product, which requires special packaging and/or labeling not provided for in this part, shall be packaged and/or labeled in accordance with requirements written into the approved outline for such product.

PART 113—STANDARD REQUIREMENTS

APPLICABILITY

Sec.

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113.35 Detection of viricidal activity.
113.36 Detection of pathogens by the chicken inoculation test.

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113.37 Detection of pathogens by the chicken embryo inoculation test.
113.38 Guinea pig safety test.
113.39 Cat safety tests.
113.40 Dog safety test.
113.41 Calf safety test.
113.42 Detection of lymphocytic choriomeningitis contamination.
113.43 Detection of chlamydial agents.
113.44 Swine safety test.
113.45 Sheep safety test.
113.46 Detection of cytopathogenic and/or hemadsorbing agents.
113.47 Detection of extraneous agents by the fluorescent antibody technique.

INGREDIENT REQUIREMENTS

113.50 Ingredients of biological products.
113.51 Requirements for primary cells used for production of biologics.
113.52 Requirements for cell lines used for production of biologics.
113.53 Requirements for ingredients of animal origin used for production of biologics.
113.54 Sterile diluent.
113.55 Detection of extraneous agents in Master Seed Virus.

LIVE BACTERIAL VACCINES

113.64 General requirements for live bacterial vaccines.
113.65 Brucella Abortus Vaccine.
113.66 Anthrax Spore Vaccine—Nonencapsulated.
113.67 Erysipelothrix Rhusiopathiae Vaccine.

INACTIVATED BACTERIAL PRODUCTS

113.85 Bacterins, toxoids, bacterin-toxoids, and bacterial extracts.
113.86 Leptospira Pomona Bacterin.
113.87 Leptospira Icterohaemorrhagiae Bacterin.
113.88 Leptospira Canicola Bacterin.
113.89 Leptospira Grippotyphosa Bacterin.
113.90 Leptospira Hardjo Bacterin.
113.91 Clostridium Chauvoei Bacterin.
113.92 Clostridium Haemolyticum Bacterin.
113.93 Clostridium Novyi Bacterin-Toxoid.
113.94 Clostridium Sordellii Bacterin-Toxoid.
113.95 Clostridium Botulinum Type C Bacterin-Toxoid.
113.96 Clostridium Perfringens Type C Toxoid and Bacterin-Toxoid.
113.97 Clostridium Perfringens Type D Toxoid and Bacterin-Toxoid.
113.98 Autogenous biologics.
113.99 Tetanus Toxoid.
113.100 Staphylococcus Aureus Bacterin-Toxoid.

113.101 Pasteurella Multocida Bacterin, Avian Isolate, Type 4.
113.102 Pasteurella Multocida Bacterin, Avian Isolate, Type 1.
113.103 Pasteurella Multocida Bacterin, Avian Isolate, Type 3.
113.104 Erysipelothrix Rhusiopathiae Bacterin.
113.105 Salmonella Typhimurium Bacterin.
113.106 Pasteurella Multocida Bacterin.
113.107 Salmonella Choleraesuis Bacterin.
113.108 Salmonella Dublin Bacterin.

KILLED VIRUS VACCINES

113.120 General requirements for killed virus vaccines.
113.121 Canine Distemper Vaccine, Killed Virus.
113.122 Canine Hepatitis Vaccine, Killed Virus.
113.123 Feline Panleukopenia Vaccine, Killed Virus.
113.124 Mink Enteritis Vaccine, Killed Virus.
113.125 Newcastle Disease Vaccine, Killed Virus.
113.126 Wart Vaccine, Killed Virus.
113.127 Encephalomyelitis Vaccine, Eastern and Western, Killed Virus.
113.128 Avian Encephalomyelitis Vaccine, Killed Virus.
113.129 Rabies Vaccine, Killed Virus.
113.130 Feline Calicivirus Vaccine, Killed Virus.
113.131 Feline Rhinotracheitis Vaccine, Killed Virus.
113.132 Bursal Disease Vaccine, Killed Virus.
113.133 Pseudorabies Vaccine, Killed Virus.
113.134 Parvovirus Vaccine, Killed Virus (Canine).

LIVE VIRUS VACCINE

113.135 General requirements for live virus vaccines.
113.136 Ovine Ecthyma Vaccine.
113.137 Distemper Vaccine— Mink.
113.138 Bluetongue Vaccine.
113.139 Feline Panleukopenia Vaccine.
113.140 Canine Hepatitis Vaccine.
113.141 Canine Distemper Vaccine (Ferret Avirulent).
113.142 Canine Distemper Vaccine (Ferret Virulent).
113.143 Encephalomyelitis Vaccine, Venezuelan.
113.144 Bovine Parainfluenza Vaccine.
113.145 Bovine Rhinotracheitis Vaccine.
113.146 Bovine Virus Diarrhea Vaccine.
113.147 Rabies Vaccine.
113.148 Measles Vaccine.
113.149 Feline Calicivirus Vaccine.
113.150 Feline Rhinotracheitis Vaccine.
113.151 Canine Parainfluenza Vaccine.
113.152 Parvovirus Vaccine (Canine).
113.153 Pseudorabies Vaccine.
113.154-113.159 [Reserved]
113.160 Avian Encephalomyelitis Vaccine.
113.161 Avian Pox Vaccine.
113.162 Bronchitis Vaccine.
113.163 Fowl Laryngotracheitis Vaccine.
113.164 Newcastle Disease Vaccine.
113.165 Marek's Disease Vaccines.
113.166 Bursal Disease Vaccine.
113.167 Tenosynovitis Vaccine.

DIAGNOSTICS AND REAGENTS

113.200 Tuberculin, Intradermic.
113.201 Pullorum antigen.
113.202 Avian mycoplasma antigen.
113.203 Tuberculin—PPD Bovis, Intradermic.

BLOOD ORIGIN PRODUCTS

113.250 General requirements for biological products of animal blood origin.
113.251 Tetanus Antitoxin.
113.252 Erysipelothrix Rhusiopathiae Antiserum.
113.253 Canine Distemper Hepatitis-Leptospira Antiserum.
113.254 Clostridium Perfringens Type C Antitoxin.
113.255 Clostridium Perfringens Type D Antitoxin.

AUTHORITY: 21 U.S.C. 151-158; 37 FR 28477, 28646; 38 FR 19141.

SOURCE: 34 FR 18004, Nov. 7, 1969, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

APPLICABILITY

§ 113.1 Compliance.

The regulations in this part apply to each serial or subserial of a licensed biological product manufactured in a licensed establishment and to each serial or subserial of a biological product in each shipment imported for distribution and sale.

§ 113.2 Testing aids.

To better ensure consistent and reproducible test results when Standard Requirement tests prescribed in the regulations are conducted, National Veterinary Services Laboratories, U.S. Department of Agriculture, may provide testing aids, when available, to licensees, permittees, and applicants for licenses and permits. Such aids shall be as follows:

(a) Supplemental Assay Method (SAM) is a technical bulletin containing detailed instructions for conducting a test. Such instructions shall be in accordance with the procedures currently being followed at National Veterinary Services Laboratories and as improved, proven procedures are developed, shall be revised and reissued prior to application.

(b) Standard Reference Preparation is a serum, virus, bacterial culture, or antigen to be used in test systems for direct comparison with serials of biological products under test.

(c) Standard Test Reagent is a serum, antitoxin, fluorescent antibody conjugate, toxin, virus, bacterial cultural, or antigen to be used in test systems but not for direct comparison with serials of biological products under test.

(d) Seed cultures are small quantities of standard organisms to be propagated by the recipient to establish a supply for use.

(e) Test Code Number is a number assigned by Veterinary Services to each test procedure specified in the Standard Requirements and in each filed Outline of Production where such test is conducted to support a request for release of a serial or subserial.

[39 FR 21041, June 18, 1974, as amended at 40 FR 758, Jan. 3, 1975; 50 FR 21799, May 29, 1985]

§ 113.3 Sampling of biological products.

Each licensee and permittee shall furnish representative samples of each serial or subserial of a biological product manufactured in the United States or imported into the United States as prescribed in this section. Additional samples may be purchased in the open market by a Veterinary Services representative.

(a) Either an employee of the Department of Agriculture, of the licensee, or of the permittee, as designated by the Deputy Administrator shall select prerelease samples of biological product in the number prescribed in paragraph (b) of this section. Each sample shall be marked for identification by the person making the selection after which they shall be packaged by the licensee or permittee, as the case may be, and forwarded to National Veterinary Services Laboratories; except that an employee of the Department may forward or deliver the samples to National Veterinary Services Laboratories if such action deemed advisable by the Deputy Administrator.

(1) Selection shall be made as follows:

(i) Nonviable liquid biological products—either bulk or final container samples of completed product shall be selected for purity, safety, or potency tests. Biological product in final container shall be selected to test for viable bacteria and fungi.

(ii) Viable liquid biological products; samples shall be in final containers and shall be randomly selected at the end of the filling operation. Bulk containers of completed product may be sampled when authorized by the Deputy Administrator.

(iii) Desiccated biological products; samples shall be in final containers and shall be randomly selected if desiccated in the final container. Biological products desiccated in bulk shall be sampled at the end of the filling operation.

(iv) Representative samples of each serial or subserial in each shipment of imported biological products shall be selected.

(2) Comparable samples shall be used by Veterinary Services, the licensee, and the permittee for similar tests.

(3) When bulk samples of completed product in liquid form are to be tested as prescribed in paragraph (a)(1) of this section, the number of such samples from each serial and the minimum quantity of product to be provided in each sample shall be stated in the filed Outline of Production.

(b) Unless otherwise prescribed by the Deputy Administrator, the number of final container samples to be selected from each serial and subserial shall be:

(1) *Vaccines:*

(i) Six multiple—dose samples of Brucella Abortus Vaccine;

(ii) Twelve samples of all other live bacterial vaccines;

(iii) Two samples of Coccidiosis Vaccine;

(iv) Eighteen samples of Rabies Vaccine, Modified Live Virus;

(v) Sixteen samples of all other vaccines consisting of live microorganisms;

(vi) Thirty single-dose or 14 multiple-dose samples of Equine Encephalomyelitis Vaccine, Killed Virus;

(vii) Twenty-two single-dose or 14 multiple-dose samples of Rabies Vaccine, Killed Virus;

(viii) Sixteen single-dose or 12 multiple-dose samples of all other vaccines consisting of killed microorganisms.

(2) *Bacterins and bacterin-toxoids:*

(i) Twelve samples of single-fraction products;

(ii) Thirteen samples of two-fraction products;

(iii) Fourteen samples of products consisting of 3 or more fractions.

(3) *Antiserums:* Twelve samples of antiserum recommended for large animals or 14 samples of antiserum recommended for small animals or the number of reagent serum samples prescribed in the filed Outline of Production for the product.

(4) *Antitoxins:*

(i) Fourteen single-dose or 12 multiple dose samples of Tetanus Antitoxin;

(ii) Twelve samples of all other antitoxins.

(5) *Toxoids:*

(i) Eighteen single-dose or 12 multiple dose samples of all toxoids.

(6) *Antigens:* Twelve samples of poultry antigens or 20 samples of tuberculin or four samples of all other diagnostic antigens.

(7) *Miscellaneous:* The number of samples from products not in the categories provided for in paragraph (b) (1), (2), (3), (4), (5), or (6) of this section shall be prescribed in the filed Outline of Production for the product.

(8) *Prelicensing and Outline of Production changes:* Samples needed to support a license application or a change in the Outline of Production for a licensed product shall be submitted only on request from Veterinary Services. Except for miscellaneous products specified in paragraph (7) of this section, the number of such samples shall be at least one and one-half times the number prescribed in this section for such product.

(9) *Sterile Diluent.* A sample of Sterile Diluent shall accompany each sample of product, other than Marek's Disease Vaccine, if such diluent is required to rehydrate or dilute the product before use. Samples of Sterile Diluent prepared for use with Marek's Disease Vaccine shall be submitted on request from Veterinary Services.

(10) *Autogenous biologics.* Two samples from each serial of autogenous biologics shall be selected; *Provided,* That, if the serial exceeds 50 containers, 12 samples shall be selected.

(c) Reserve samples shall be selected from each serial and subserial of every biological product. Such samples shall be selected at random from final containers of completed product by an employee of the Department, of the licensee, or of the permittee, as designated by the Deputy Administrator.

Each sample shall:

(1) Consist of 5 single dose or 2 multiple dose packages as the case may be;

(2) Be adequate in quantity for appropriate examination and testing;

(3) Be truly representative and in final containers;

(4) Be held in a special compartment or equivalent set aside by the licensee or permittee, for holding these samples under refrigeration at the storage temperature recommended on the labels for 6 months after the expiration date stated on the labels. These samples shall be stored in this manner and shall be delivered to Veterinary Services upon request.

(Approved by the Office of Management and Budget under control number 0579-0013)

[38 FR 29886, Oct. 30, 1973, as amended at 40 FR 758, Jan. 3, 1975; 40 FR 20066, May 8, 1975; 40 FR 45420, Oct. 2, 1975; 40 FR 49768, Oct. 24, 1975; 41 FR 56627, Dec. 29, 1976; 48 FR 9506, Mar. 7, 1983; 48 FR 57473, Dec. 30, 1983; 50 FR 21799, May 29, 1985]

§ 113.4 Exemptions to tests.

(a) The test methods and procedures contained in all applicable Standard Requirements shall be complied with unless otherwise exempted by the Deputy Administrator and provided that such exemption is noted in the filed Outline of Production for the product.

(b) Test methods and procedures by which the biological products shall be evaluated shall be designated in the Outline of Production for such products.

[38 FR 29887, Oct. 30, 1973]

§ 113.5 General testing.

(a) No biological product shall be released prior to the completion of tests prescribed in a filed Outline of Production or Standard Requirements for the product to establish the product to be pure, safe, potent, and efficacious.

(b) Tests of biological products shall be observed by a competent employee of the manufacturer during all critical periods. A critical period shall be the time when certain specified reactions must occur in required tests to properly evaluate the results.

(c) Records of all tests shall be kept in accordance with Part 116 of this chapter. Results of all required tests prescribed in the filed Outline of Production or the Standard Requirements for the product shall be submitted to Veterinary Services. Blank forms shall be furnished upon request to Veterinary Services.

(d) When the initial or any subsequent test is declared a "No test," the reasons shall be reported in the test records, the results shall not be considered as final, and the test may be repeated.

(e) When new test methods are developed and approved by Veterinary Services, biological products tested thereafter shall be evaluated by such methods, and if not found to be satisfactory when so tested shall not be released.

(Approved by the Office of Management and Budget under control number 0579-0059)

[34 FR 18004, Nov. 4, 1969, as amended at 39 FR 25463, July 11, 1974; 40 FR 45420, Oct. 2, 1975; 40 FR 46093, Oct. 6, 1975; 41 FR 6751, Feb. 13, 1976; 48 FR 57473, Dec. 30, 1983]

§ 113.6 Veterinary Services testing.

A biological product shall with reasonable certainty yield the results intended when used as recommended or suggested in its labeling or proposed labeling prior to the expiration date.

(a) The Deputy Administrator is authorized to cause a biological product, manufactured in the United States or imported into the United States, to be examined and tested for purity, safety, potency, or efficacy; in which case, the licensee or permittee shall withhold such product from the market until a determination has been made.

(b) The final results of each test conducted by the licensee and Veterinary Services shall be considered in evaluating a biological product. A serial or subserial which has been found unsatisfactory by a required test prescribed in a filed Outline of Production or Standard Requirement is not in compliance with the regulations and shall not be released for market.

[34 FR 18004, Nov. 7, 1969, as amended at 40 FR 45420, Oct. 2, 1975; 40 FR 53378, Nov. 18, 1975; 41 FR 6751, Feb. 13, 1976]

§ 113.7 Multiple fractions.

(a) When a biological product contains more than one immunogenic fraction, the completed product shall be evaluated by tests applicable to each fraction.

(b) When similar potency tests are required for more than one fraction of a combination biological product, different animals must be used to evaluate each fraction except when written Standard Requirements or outlines of production make provisions and set forth conditions for use of the same animals for testing different fractions.

(c) When the same safety test is required for more than one fraction, requirements are fulfilled by satisfactory results from one test of the completed product.

(d) When an inactivated fraction(s) is used as a diluent for a live virus fraction(s), the inactivated fraction(s) may be tested separately and the live virus fraction(s) may be tested separately: *Provided*, That, the viricidal test requirements prescribed in § 113.85 are complied with.

(e) Virus titrations for a multivirus product shall be conducted by methods which will quantitate each virus.

[34 FR 18004, Nov. 7, 1969, as amended at 40 FR 46093, Oct. 6, 1975]

§ 113.8 In vitro tests in lieu of animal tests for immunogenicity.

(a) Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing seed for production when specified in the Standard Requirements or in a filed Outline of Production. The Deputy Administrator may exempt a product from a required animal test for release when an evaluation can with reasonable certainty be made by:

(1) Subjecting the Master Seed to the applicable requirements prescribed in § 113.135 or § 113.64;

(2) Testing the Master Seed for immunogenicity in a manner acceptable to Veterinary Services;

(3) Establishing a satisfactory count or titer based on a predetermined protective dose plus an adequate overage allowance for adverse conditions and test error; and

(4) Conducting counts or titrations on each serial and subserial in an accepted test system.

(b) Each serial and subserial derived from an approved Master Seed shall be evaluated by a test procedure acceptable to Veterinary Services and either released to the firm for marketing or withheld from the market on the basis of the results of the test when compared with the required minimum. The evaluation of such products shall be made in accordance with this paragraph.

(1) If the initial test shows the count or titer to equal or exceed the required minimum, the serial or subserial is satisfactory without additional testing.

(2) If the initial test shows the count or titer to be lower than the required minimum, the serial or subserial may be retested, using double the number of samples. The average counts or titers obtained in the retests shall be determined. If the average is less than the required minimum, the serial or subserial is unsatisfactory without further consideration.

(3) If the average is equal to or greater than the required minimum, the following shall apply to live virus vaccines:

(i) If the difference between the average titer obtained in the retests and the titer obtained in the initial test is $10^{0.7}$ or greater, the initial titer may be considered a result of test system error and the serial or subserial considered satisfactory for virus titer.

(ii) If the difference between the average titer obtained in the retests and the titer obtained in the initial test is less than $10^{0.7}$, a new average shall be determined using the titers obtained in all tests. If the new average is below the required minimum, the serial or subserial is unsatisfactory.

(4) If the average is equal to or greater than the required minimum, the following shall apply to bacterial vaccines:

(i) If the average count obtained in the retests is at least three times the count obtained in the initial test, the initial count may be considered a result of test system error and the serial or subserial considered satisfactory for bacterial count.

(ii) If the average count obtained in the retests is less than three times the count obtained in the initial test, a new average shall be determined using the counts obtained in all tests. If the new average count is below the required minimum, the serial or subserial is unsatisfactory.

(5) *Exceptions.* When a product is evaluated in terms other than $\log_{10}$ virus titer values or organism count, a range shall be established to substitute for use in paragraphs (b)(3) or (4) of this section and specified in the Outline of Production.

(c) Final container samples of completed product derived from Master Seed found immunogenic in accordance with paragraph (a) of this section and found satisfactory in accordance with paragraph (b) of this section may also be subjected to an animal potency test by Veterinary Services as provided in this paragraph. Products shall be used according to label directions including dose(s) and route of administration.

(1) A one stage test using 20 vaccinates and 5 controls or a two stage test using 10 vaccinates and 5 controls for each stage shall be used. The criteria used for judging the specific response in the controls and vaccinates shall be in accordance with the test protocol used in the Master Seed immunogenicity test.

(2) If at least 80 percent of the controls do not show specific responses to challenge, the test is inconclusive and may be repeated. If a vaccinate shows the specific responses to challenge expected in the controls, the vaccinate shall be listed as a failure.

(3) The results of the testing shall be evaluated according to the following table:

CUMULATIVE TOTALS

Stage	Number of animals	Failures for satisfactory serials	Failures for unsatisfactory serials
1	10	1 or less	3 or more.
2 (or 1)	20	4 or less	5 or more.

(4) When a serial has been found unsatisfactory for potency by the test provided in paragraphs (c)(1), (2), and (3) of this section, the serial shall be withheld from the market and the following actions taken:

(i) The Deputy Administrator shall require that at least two additional serials prepared with the same Master Seed be subjected to similar animal potency tests by Veterinary Services or the licensee or both.

(ii) If another serial is found unsatisfactory for potency, the product shall be removed from the market while a reevaluation of the product is made and the problem is resolved.

[49 FR 22625, May 31, 1984]

§ 113.9 New potency test.

A potency test written into the filed Outline of Production for a product shall be considered confidential information by Veterinary Services until at least two additional product licenses are issued for the product or unless use of the test is authorized by the licensee, in which case, such potency test may be published as part of the Standard Requirement for the product.

(a) Until a potency test is published as part of the Standard Requirement for the product, reference to such a test shall be made in the filed Outline of Production and the test shall be conducted.

(b) When a potency test has been published as part of the Standard Requirement, such test shall be conducted unless the product is specifically exempted as provided in § 113.4.

[40 FR 14084, Mar. 28, 1975]

§ 113.10 Testing of bulk material for export or for further manufacture.

When a product is prepared in a licensed establishment for export in large multiple-dose containers as provided in § 112.8(d) or (e) of this subchapter or for further manufacturing purposes as provided in § 114.3(d) of this subchapter, samples of the bulk material shall be subjected to all required tests prescribed in the filed Outline of Production or Standard Requirements for the product. Samples of concentrated liquid product shall be diluted to a volume equal to the contents of the sample times the concentration factor prior to initiating potency tests.

[49 FR 45846, Nov. 21, 1984]

STANDARD PROCEDURES

§ 113.25 Culture media for detection of bacteria and fungi.

(a) Ingredients for which standards are prescribed in the United States Pharmacopeia, or elsewhere in this part, shall conform to such standards. In lieu of preparing the media from the individual ingredients, they may be made from dehydrated mixtures which, when rehydrated with purified water, have the same or equivalent composition as such media and have growth-promoting buffering, and oxygen tension-controlling properties equal to or better than such media. The formulas for the composition of the culture media prescribed in §§ 113.26 and 113.27 are set forth in the United States Pharmacopeia, 19th Edition.

(b) The licensee shall test each quantity of medium prepared at one time from individual ingredients and the first quantity prepared from each lot of commercial dehydrated medium for growth-promoting qualities. If any portion of a lot of commercial dehydrated medium is held for 90 days or longer after being so tested, it shall be retested before use. Two or more strains of micro-organisms that are exacting in their nutritive requirements shall be used. More than one dilution shall be used to demonstrate the adequacy of the medium to support the growth of a minimum number of micro-organisms.

(c) The sterility of the medium shall be confirmed by incubating an adequate number of test vessels and examining each for growth. Additional control may be used by incubation of representative uninoculated test vessels for the required incubation period during each test.

(d) A determination shall be made by the licensee for each biological product of the ratio of inoculum to medium which shall result in sufficient dilution of such product to prevent bacteriostatic and fungistatic activity. The determination may be made by tests on a representative biological product for each group of comparable products containing identical preservatives at equal or lower concentrations. Inhibitors or neutralizers of preservatives, approved by the Deputy Administrator, may be considered in determining the proper ratio.

[35 FR 16039, Oct. 13, 1970, as amended at 37 FR 2430, Feb. 1, 1972; 41 FR 27715, July 6, 1976]

§ 113.26 Detection of viable bacteria and fungi except in live vaccine.

Each serial and subserial of biological product except live vaccines shall be tested as prescribed in this section unless otherwise specified by the Deputy Administrator. When cell lines, primary cells, or ingredients of animal origin used in the preparation of a biological product are required to be free of viable bacteria and fungi, they shall also be tested as prescribed in this section.

(a) The media to be used shall be as follows:

(1) Fluid Thioglycollate Medium with 0.5 percent beef extract shall be used to test for bacteria in biological products containing clostridial toxoids, bacterins, and bacterin-toxoids.

(2) Fluid Thioglycollate Medium with or without 0.5 percent beef extract shall be used to test for bacteria in biological products other than clostridial toxoids, bacterins, and bacterin-toxoids.

(3) Soybean-Casein Digest Medium shall be used to test biological products for fungi; provided, that Fluid Thioglycollate Medium without beef extract shall be substituted when testing biological products containing mercurial preservatives.

(b) Test procedure:

(1) Ten test vessels shall be used for each of two media selected in accordance with paragraph (a)(1), (a)(2), or (a)(3) of this section. Each test vessel shall contain sufficient medium to negate the bacteriostatic or fungistatic activity in the inoculum as determined in § 113.25(d).

(2) Inoculum:

(i) When completed product is tested, 10 final container samples from each serial and each subserial shall be tested. One ml from each sample shall be inoculated into a corresponding individual test vessel of culture medium: *Provided*, That, if each final container sample contains less than 2 ml, one-half of the contents shall be used as inoculum for each test vessel.

(ii) When cell lines, primary cells, or ingredients of animal origin are tested, at least a 20 ml test sample from each lot shall be tested. One ml shall be inoculated into each test vessel of medium.

(3) Incubation shall be for an observation period of 14 days at 30° to 35° C. to test for bacteria and 14 days at 20° to 25° C. to test for fungi.

(4) If the inoculum renders the medium turbid so that the absence of growth cannot be determined by visual examination, subcultures shall be made on the seventh to eleventh day from biological products prepared from clostridial toxoids, bacterins, and bacterin-toxoids and the third to seventh day for other biological products. Portions of the turbid medium in amounts of not less than 1.0 ml. shall be transferred to 20 to 25 ml. of fresh medium, and incubated the balance of the 14-day period.

(c) Examine the contents of all test vessels for macroscopic microbial growth during the incubation period. When demonstrated by adequate controls to be invalid, the test may be repeated. For each set of test vessels representing a serial or subserial in a valid test, the following rules shall apply:

(1) If no growth is found in any test vessel, the serial or subserial meets the requirements of the test.

(2) If growth is found in any test vessel, one retest to rule out faulty technique may be conducted using 20 unopened final container samples.

(3) If growth is found in any test vessel of the final test, the serial, subserial, or ingredients to be used in the preparation of a biological product, as the case may be, is unsatisfactory.

[35 FR 16039, Oct. 13, 1970, as amended at 37 FR 2430, Feb. 1, 1972; 39 FR 21042, June 18, 1974; 40 FR 758, Jan. 3, 1975; 40 FR 14084, Mar. 28, 1975]

§ 113.27 Detection of extraneous viable bacteria and fungi in live vaccines.

Unless otherwise specified by the Deputy Administrator or elsewhere exempted in this part, each serial and subserial of live vaccine and each lot of Master Seed Virus and Master Seed Bacteria shall be tested for extraneous viable bacteria and fungi as prescribed in this section. A Master Seed found unsatisfactory shall not be used in vaccine production and a serial found unsatisfactory shall not be released.

(a) *Live viral vaccines.* Each serial and subserial of live viral vaccine shall be tested for purity as prescribed in this paragraph. However, products of chicken embryo origin recommended for administration other than by parenteral injection may be tested as provided in paragraph (e) of this section.

(1) Soybean Casein Digest Medium shall be used.

(2) Ten final container samples from each serial and subserial shall be tested.

(3) Immediately prior to starting the test, frozen liquid vaccine shall be thawed, and desiccated vaccine shall be rehydrated as recommended on the label with accompanying diluent or with sterile purified water.

(4) To test for bacteria, place 0.2 ml of vaccine from each final container into a corresponding individual vessel containing at least 120 ml of Soybean Casein Digest Medium. Additional medium shall be used if the determination required in § 113.25(d) indicates the need for a greater dilution of the product. Incubation shall be at 30°to 35° C for 14 days.

(5) To test for fungi, place 0.2 ml of vaccine from each final container sample into a corresponding individual vessel containing at least 40 ml of Soybean Casein Digest Medium. Additional medium shall be used if the determination required in § 113.25(d) indicates the need for a greater dilution of the product. Incubation shall be at 20° to 25° C for 14 days.

(6) Examine the contents of all test vessels macroscopically for microbial growth at the end of the incubation period. If growth in a vessel cannot be reliably determined by visual examination, judgment shall be confirmed by subcultures, microscopic examination, or both.

(7) For each set of test vessels representing a serial or subserial tested according to these procedures, the following rules shall apply:

(i) If growth is found in 2 or 3 test vessels of the initial test, 1 retest to rule out faulty technique may be conducted using 20 unopened final container samples.

(ii) If no growth is found in 9 or 10 of the test vessels in the initial test, or 19 or 20 vessels in the retest, the serial or subserial meets the requirements of the test.

(iii) If growth is found in four or more test vessels in the initial test, or two or more in a retest, the serial or subserial is unsatisfactory.

(b) *Live bacterial vaccines.* Each serial or subserial of live bacterial vaccine shall be tested for purity as prescribed in this paragraph.

(1) Soybean Casein Digest Medium and Fluid Thioglycollate Medium shall be used.

(2) Ten final container samples from each serial and subserial shall be tested.

(3) Immediately prior to starting the test, frozen liquid vaccine shall be thawed, and desiccated vaccine shall be rehydrated as recommended on the label with accompanying diluent or with sterile purified water. Product recommended for mass vaccination shall be rehydrated at the rate of 30 ml sterile purified water per 1,000 doses.

(4) To test for extraneous bacteria, place 0.2 ml of vaccine from each final container into a corresponding individual vessel containing at least 40 ml of Fluid Thioglycollate Medium. Additional medium shall be used if the determination require in § 113.25(d) indicates the need for a greater dilution of the product. Incubation shall be at 30° to 35° C for 14 days.

(5) To test for extraneous fungi, place 0.2 ml of vaccine from each final container into a corresponding individual vessel containing at least 40 ml of Soybean Casein Digest Medium. Additional medium shall be used if the determination required in § 113.25(d) indicates the need for a greater dilution of the product. Incubation shall be at 20° to 25° C for 14 days.

(6) Examine the contents of all test vessels macroscopically for atypical microbial growth at the end of the incubation period. If growth of extraneous microorganisms cannot be reliably determined by visual examination, judgment shall be confirmed by subculturing, microscopic examination, or both.

(7) For each set of test vessels representing a serial or subserial tested according to these procedures, the following rules shall apply:

(i) If extraneous growth is found in 2 or 3 test vessels of the initial test, 1 retest to rule out faulty technique may be conducted using 20 unopened final container samples.

(ii) If no extraneous growth is found in 9 or 10 test vessels in the initial test, or 19 or 20 vessels in the retest, the serial or subserial meets the requirements of the test.

(iii) If extraneous growth is found in 4 or more test vessels in the initial test, or 2 or more in a retest, the serial or subserial is unsatisfactory.

(c) *Master Seed Virus*. Not less than 4 ml of each lot of Master Seed Virus shall be tested. Frozen liquid Master Seed Virus shall be thawed, and desiccated Master Seed Virus shall be rehydrated with Soybean Casein Digest Medium immediately prior to starting the test.

(1) To test for bacteria, place 0.2 ml of the sample of Master Seed Virus into 10 individual vessels each containing at least 120 ml of Soybean Casein Digest Medium. Incubation shall be at 30° to 35° C for 14 days.

(2) To test for fungi, place 0.2 ml of the sample of Master Seed Virus into 10 individual vessels each containing at least 40 ml of Soybean Casein Digest Medium. Incubation shall be at 20° to 25° C for 14 days.

(3) Examine the contents of all test vessels macroscopically for microbial growth at the end of the incubation period. If growth in a vessel cannot be reliably determined by visual examination, judgment shall be confirmed by subcultures, microscopic examination, or both.

(4) For each set of test vessels representing a lot of Master Seed Virus tested according to these procedures, the following rules shall apply:

(i) If growth is found in any test vessel of the initial test, one retest to rule out faulty technique may be conducted using a new sample of Master Seed Virus.

(ii) If growth is found in any test vessel of the final test, the lot of Master Seed Virus is unsatisfactory.

(d) *Master Seed Bacteria*. Not less than 4 ml of each lot of Master Seed Bacteria shall be tested. Frozen liquid Master Seed Bacteria shall be thawed, and desiccated Master Seed Bacteria shall be rehydrated with sterile purified water immediately prior to starting the test.

(1) To test for extraneous bacteria, place 0.2 ml of the sample of Master Seed Bacteria into 10 individual vessels each containing at least 40 ml of Fluid Thioglycollate Medium. Incubation shall be at 30° to 35° C for 14 days.

(2) To test for extraneous fungi, place 0.2 ml of the sample of Master Seed Bacteria into 10 individual vessels each containing at least 40 ml of Soybean Casein Digest Medium. Incubation shall be at 20° to 25° C for 14 days.

(3) Examine the contents of all test vessels macroscopically for atypical microbial growth at the end of the incubation period. If growth of extraneous microorganisms cannot be reliably determined by visual examination, judgment shall be confirmed by subcultures, microscopic examination, or both.

(4) For each set of test vessels representing a lot of Master Seed Bacteria tested according to these procedures, the following rules shall apply:

(i) If extraneous growth is found in any test vessel of the initial test, one retest to rule out faulty technique may be conducted using a new sample of Master Seed Bacteria.

(ii) If extraneous growth is found in any test vessel of the final test, the lot of Master Seed Bacteria is unsatisfactory.

(e) Live viral vaccines of chicken embryo origin recommended for administration other than by parenteral injection, which were not tested or have not been found free of bacteria and fungi by the procedures prescribed in paragraph (a) of this section, may be tested according to the procedures prescribed in this paragraph.

(1) Brain Heart Infusion Agar shall be used with 500 Kinetic (Kersey) units of penicillinase per ml of medium added just prior to pouring the plates.

(2) Ten final containers from each serial and each subserial shall be tested.

(3) Immediately prior to starting the test, frozen liquid vaccine shall be thawed, and lyophilized vaccine shall be rehydrated to the quantity recommended on the label using the accompanying sterile diluent or sterile purified water. Product recommended for mass vaccination shall be rehydrated at the rate of 30 ml sterile purified water per 1,000 doses.

(4) From each container sample, each of 2 plates shall be inoculated with vaccine equal to 10 doses if the vaccine is recommended for poultry or 1 dose if the vaccine is recommended for other animals. Twenty ml of medium shall be added to each plate. One plate shall be incubated at 30° to 35° for 7 days and the other plate shall be incubated at 20° to 25° C for 14 days.

(5) Colony counts shall be made for each plate at the end of the incubation period. An average colony count for the 10 samples representing the serial or subserial shall be made for each incubation condition.

(6) For each set of test vessels representing a serial or subserial tested according to these procedures, the following rules shall apply:

(i) If the average count at either incubation condition exceeds 1 colony per dose for vaccines recommended for poultry, or 10 colonies per dose for vaccines recommended for other animals in the initial test, 1 retest to rule out faulty technique may be conducted using 20 unopened final containers.

(ii) If the average count at either incubation condition of the final test for a serial or subserial exceeds 1 colony per dose for vaccines recommended for poultry, or 10 colonies per dose for vaccines recommended for other animals, the serial or subserial is unsatisfactory.

[48 FR 28430, June 22, 1983]

§ 113.28 Detection of mycoplasma contamination.

The heart infusion test, using heart infusion broth and heart infusion agar, provided in this section shall be conducted when a test for mycoplasma contamination is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) Media additives provided in this paragraph shall be prepared as follows:

(1) DPN-Cysteine Solution:

(i) Use Nicotinamide adenine dinucleotide (oxidized) and L-Cysteine hydrochloride.

(ii) Prepare 1 gram/100 milliliters (ml) purified water (1 percent solution) of each. Mix the solutions together; the cysteine reduces the DPN. Filter sterilize, dispense in appropriate amounts and store frozen at −20 degrees centigrade.

(2) Inactivated horse serum—horse serum which has been inactivated at 56° C for 30 minutes.

(b) Heart infusion broth shall be prepared as provided in this paragraph.

(1) Dissolve in 970 ml of purified water, 25 grams of heart infusion broth, 10 grams of proteose peptone No. 3, and either 5 grams of yeast autolysate or 5 ml of fresh yeast extract.

(2) Add the following:

1 percent tetrazolium chloride (ml)	5.5
1 percent thallium acetate (ml)	25
Penicillin (units)	500,000
Inactivated horse serum (ml)	100

(3) Adjust pH to 7.9 with NaOH, filter sterilize, and dispense 100 ml aliquots into 125 ml flasks and store until needed.

(4) Add 2 ml of DPN-Cysteine solution to each 100 ml of broth on day of use.

(c) Heart Infusion Agar shall be prepared as provided in this paragraph.

(1) Dissolve in 900 ml of purified water by boiling the following:

Heart infusion agar (g)	25
Heart-infusion broth (g)	10
Proteose peptone No. 3 (g)	10
1 pct thallium acetate (ml)	25

(2) Cool the medium and adjust pH to 7.9 with NaOH.

(3) Autoclave the medium.

(4) Cool the medium 30 minutes in a 56° C waterbath.

(5) Dissolve 5 grams of yeast autolysate in 100 ml of distilled water, filter sterilize, and add to the medium.

(6) Add to the medium:

126 ml of inactivated horse serum
21 ml of DPN-Cysteine solution
525,000 units of Penicillin.

Dispense 10 ml aliquots into 60×15 mm disposable culture dishes or petri dishes.

(d) The test procedure provided in this paragraph shall be followed when conducting the mycoplasma detection test.

(1) Preparation of inoculum. Immediately prior to starting the test, frozen liquid vaccine shall be thawed, and lyophilized vaccine shall be rehydrated to the volume recommended on the label with mycoplasma medium. In the case of a lyophilized biological product, e.g., 1,000 dose vial of poultry vaccine to be administered via the drinking water, the vaccine shall be rehydrated to 30 ml with mycoplasma medium. In the case of a cell line or a sample of primary cells, the inoculum shall consist of the resuspended cells. Control tests shall be established as provided in paragraph (d)(4) of this section.

(2) Inoculation of plate. Plate 0.1 ml of inoculum on an agar plate and make a short, continuous streak across the plate with a pipet. Tilt the plate to allow the inoculum to flow over the surface.

(3) Inoculation of flask of medium. Transfer 1 ml of the inoculum into a flask containing 100 ml mycoplasma medium and mix thoroughly. Incubate the flask at 33 to 37° C for 14 days during which time, one of four agar plates shall be streaked with 0.1 ml of material from the incubating flask of inoculated medium on the 3d day, one on the 7th day, one on the 10th day, and one on the 14th day post-inoculation.

(4) Control tests shall be conducted simultaneously with the detection test using techniques provided in paragraphs (d)(2) and (3) of this section, except the inoculum for the positive control test shall be selected mycoplasma cultures and the negative control test shall be uninoculated medium from the same lot used in the detection test.

(5) All plates shall be incubated in a high humidity, 4-6 percent CO_2 atmosphere at 33° to 37° C for 10-14 days and examined with a stereoscopic microscope at 35x to 100x or with a regular microscope at 100x.

(e) Interpretation of test results.

(1) If growth appears on at least one of the plates in the positive control test and does not appear on any of the plates in the negative control test, the test is valid.

(2) If mycoplasma colonies are found on any of the plates inoculated with material being tested, the results are positive for mycoplasma contamination.

[38 FR 29887, Oct. 30, 1973, as amended at 41 FR 6752, Feb. 13, 1976; 41 FR 32882, Aug. 6, 1976]

§ 113.29 Determination of moisture content in desiccated biological products.

Methods provided in this section shall be used when a determination of moisture content in desiccated biological products is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) Final container samples of completed product shall be tested. Individual samples having a low net weight shall be pooled at the time of testing in order to attain a minimum of 100 milligrams of dried product.

(b) The weight loss of the sample(s) due to drying to a constant weight in a vacuum oven shall be determined. The recommended equipment is as follows:

(1) Numbered, low-form, flat-bottom weighing dishes with tight-fitting lids.

(2) Vacuum oven equipped with a vacuum pump, accurate thermometer, vacuum gage, and thermostat. A suitable drying device shall be attached to the inlet valve of the oven. The vacuum system shall have a manometer and flowmeter for proper regulation of flow and pressure.

(3) Balance, accurate to 0.1 mg (rated precision ±0.01 mg.

(4) Dry box or hood equipped with a suitable drying device and hygrometer to assure a relative humidity of 0 to 10 percent. The box should be sufficient in size to allow for the convenient transfer of samples and, if possible, incorporation of the balance and vacuum oven.

(5) If needed, a desiccator jar equipped with P_2O_5 plus $CaSO_4$ or $CaCl_2$ drying agent with indicator.

(c) Test procedure:

(1) Thoroughly cleaned weighing dishes shall be dried approximately 3 hours at 60° C under vacuum or for 1 hour at 100° C or higher in a drying oven. Immediately upon removal, the dishes shall be placed in a dry atmosphere and allowed to cool to room temperature. The tare weight of each weighing dish shall be determined as rapidly as possible. All manipulations of weighing dishes shall be made with tongs or while wearing gloves.

(2) The relative humidity of the dry box shall be reduced to 0 to 10 percent to assure a low level of moisture in the box during the time of transfer of the sample to the weighing dish.

(3) After the sample container has equilibrated in the dry atmosphere, the vacuum shall be released slowly allowing dry air to enter the bottle.

(4) The stopper shall be removed and the sample plug broken up with a spatula.

(5) The sample shall be rapidly transferred to a previously weighed and marked weighing dish and covered with its lid.

(6) After transfer has been completed, the weighing dish with its contents shall be weighed immediately giving the gross weight of the dish and sample. This weight minus the tare weight of the weighing dish is the sample weight.

(7) The lids shall be removed and placed with their matched weighing dishes in the vacuum oven. The pressure in the oven shall be reduced to 1 millimeter of mercury or less and the thermostat set at 60° C. A small amount of dry air shall be allowed to bleed into the oven during the drying period and the reduced pressure maintained by continuous operation of the vacuum pump.

(8) After 24 hours of drying time, the vacuum pump shall be stopped and dry air allowed to continually bleed into the oven with an increased flow rate until the pressure inside of the oven has been equalized with the atmosphere.

(9) The lids shall be immediately replaced in the normal closed position and the dishes placed in an efficient desiccator and allowed to cool to room temperature.

(10) Immediately upon reaching ambient temperature, each weighing dish containing the sample shall be removed from the desiccator and weighed as rapidly as possible. This weight subtracted from the gross weight obtained in accordance with paragraph (c)(6) of this section gives the equivalent weight of moisture lost upon drying.

(11) The steps prescribed in paragraphs (c)(8), (9), and (10) of this section may be repeated if experience has indicated that the particular product will not dry to a constant weight in the first 24 hours.

(12) Refer to paragraphs (c)(6) and (10) of this section. The equivalent weight of moisture divided by the sample weight times 100 equals the percentage of moisture in the original sample.

[38 FR 29887, Oct. 30, 1973]

§ 113.30 Detection of Salmonella contamination.

The test for detection of Salmonella contamination provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) Samples shall be collected from the bulk suspension before bacteriostatic or bactericidal agents have been added. When tissue culture products are to be tested, 1 ml of tissue extract used as the source of cells or 1 ml of the minced tissue per se shall be tested.

(b) Five ml of the liquid vaccine suspension shall be used to inoculate each 100 ml of liquid broth medium (tryptose and either selenite F or tetrathionate). The inoculated media shall be incubated 18-24 hours at 35-37° C.

(c) Transfers shall be made to either MacConkey agar or Salmonella-Shigella agar, incubated for 18-24 hours and examined.

(d) If no growth typical of Salmonella is noted, the plates shall be incubated an additional 18-24 hours and again examined.

(e) If suspicious colonies are observed, further subculture on suitable media shall be made for positive identification. If Salmonella is found, the bulk suspension is unsatisfactory.

[38 FR 29888, Oct. 30, 1973]

§ 113.31 Detection of avian lymphoid leukosis.

The complement-fixation test for detection of avian lymphoid leukosis provided in this section shall be conducted on all biological products containing virus which has been propagated in substrates of chicken origin: *Provided*, An inactivated viral product shall be exempt from this requirement if the licensee can demonstrate to Veterinary Services that the agent used to inactivate the vaccine virus would also inactivate lymphoid leukosis virus.

(a) Propagation of contaminating lymphoid leukosis viruses, if present, shall be done in chick embryo cell cultures.

(1) Each vaccine virus, cytopathic to chick embryo fibroblast cells, shall be effectively neutralized, inactivated, or separated so that minimal amounts of lymphoid leukosis virus can be propagated on cell culture during the 21-day growth period. If a vaccine virus cannot be effectively neutralized, inactivated, or separated, a sample of another vaccine prepared the same week from material harvested from each source flock (or other sampling procedure acceptable to Veterinary Services) used for the preparation of the questionable vaccine virus that cannot be neutralized, inactivated, or separated shall be tested each week during the preparation of such questionable vaccine.

(2) When cell cultures are tested, 5 ml of the final cell suspension as prepared for seeding of production cell cultures shall be used as inoculum. When vaccines are tested, the equivalent of 200 doses of Newcastle disease vaccine or 500 doses of other vaccines for use in poultry, or one dose of vaccine for use in other animals shall be used as inoculum. Control cultures shall be prepared from the same cell suspension as the cultures for testing the vaccine.

(3) Uninoculated chick embryo fibroblast cell cultures shall act as negative controls. One set of chick fibroblast cultures inoculated with subgroup A virus and another set inoculated with subgroup B virus shall act as positive controls, A and B respectively.

(4) The cell cultures shall be propagated at 35-37° C for at least 21 days. They shall be passed when necessary to maintain viability and samples harvested from each passage shall be tested for group specific antigen.

(b) The microtiter complement-fixation test shall be performed using either the 50 percent or the 100 percent hemolytic end point technique to determine complement unitage. Five 50 percent hemolytic units or two 100 percent hemolytic units of complement shall be used for each test.

(1) All test materials, including positive and negative controls, shall be stored at −60° C or colder until used in the test. Before use, each sample shall be thawed and frozen three times to disrupt intact cells and release the group specific antigen.

(2) The antiserum used in the microtiter complement-fixation test shall be

a standard reagent supplied or approved by the Veterinary Services. Four units of antiserum shall be used for each test.

(3) Presence of complement-fixing activity in the harvested samples (from passages) at the 1:4 or higher dilution, in the absence of anticomplementary activity, shall be considered a positive test unless the activity can definitely be established to be caused by something other than lymphoid leukosis virus, subgroups A and/or B. Activity at the 1:2 dilution shall be considered suspicious and the sample further subcultured to determine presence or absence of the group specific antigen.

(4) Biological products or primary cells which are found contaminated with lymphoid leukosis viruses are unsatisfactory. Source flocks from which contaminated material was obtained are also unsatisfactory.

[38 FR 29888, Oct. 30, 1973, as amended at 38 FR 32917, Nov. 29, 1973; 39 FR 21042, June 18, 1974]

§ 113.32 Detection of Brucella contamination.

The test for detection of Brucella contamination provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in a filed Outline of Production for the product.

(a) One ml of the minced tissue used as the source of cells or 1 ml of the extract of the tissue prior to the addition of antibiotics, diluent and stabilizer, shall be inoculated onto each of three tryptose agar plates and incubated in a 10 percent CO_2 atmosphere at a temperature of 35-37° C for at least 7 days.

(b) If colonies are identified as Brucella, the biological product is unsatisfactory.

(c) If colonies suspicious of Brucella are observed but cannot be identified as a Brucella species, either

(1) The biological product shall be regarded as unsatisfactory and destroyed; or

(2) Further subculture or other procedures shall be carried out until a positive identification can be made.

[38 FR 29888, Oct. 30, 1973]

§ 113.33 Mouse safety tests.

One of the mouse safety tests provided in this section shall be conducted when such test is prescribed in a Standard Requirement or in the filed Outline of Production for a biological product recommended for animals other than poultry: *Provided,* That if the inherent nature of one or more ingredients makes the biological product lethal or toxic for mice but not lethal or toxic for the animals for which it is recommended, the licensee shall demonstrate the safety of such product by an acceptable test written into such Outline of Production.

(a) Final container samples of completed product from live virus vaccines shall be tested for safety using young adult mice in accordance with the test provided in this paragraph.

(1) Vaccine, prepared for use as recommended on the label, shall be tested. Eight mice shall be inoculated intracerebrally with 0.03 ml and eight mice shall be inoculated intraperitoneally with 0.5 ml. Both groups shall be observed for 7 days.

(2) If unfavorable reactions attributable to the product occur in two or more mice in either group during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur in two or more mice in either group, the test shall be declared inconclusive and may be repeated: *Provided,* That, if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

(b) Bulk or final container samples of completed product from liquid products, such as but not limited to antiserums and bacterins, shall be tested for safety in accordance with the test provided in this paragraph.

(1) Unless otherwise prescribed in the Standard Requirement or approved in a filed Outline of Production for the product, a 0.5 ml dose shall be injected intraperitoneally or subcutaneously into eight mice and the animals observed for 7 days.

(2) If unfavorable reactions attributable to the product occur in any of the mice during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which

are not attributable to the product occur, the test shall be declared inconclusive and may be repeated: *Provided*, That, if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

[38 FR 34727, Dec. 18, 1973, as amended at 39 FR 16857, May 10, 1974]

§ 113.34 Detection of hemagglutinating viruses.

The test for detection of hemagglutinating viruses provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) Final container samples of completed product rehydrated as recommended on the label shall be used as inoculum: *Provided*, That poultry vaccines distributed without diluent shall be rehydrated with 30 ml of sterile distilled water per 1,000 doses and used as inoculum. When one or more fractions are to be used in combination with Newcastle Disease Vaccine, test samples shall be collected from bulk suspensions of each prior to mixing with the Newcastle Disease Vaccine.

(b) Each of ten 9- to 10-day-old embryonating eggs from Newcastle disease susceptible flocks shall be inoculated into the allantoic cavity with 0.2 ml of the undiluted inoculum.

(1) Test five uninoculated embryos of the same age and from the same flock as those used for the test as negative controls.

(2) Test an allantoic fluid sample of Newcastle disease virus as a positive control.

(c) Three to five days post-inoculation, a sample of allantoic fluid from each egg shall be tested separately by a rapid plate test for hemagglutinating activity using a 0.5 percent suspension of fresh chicken red blood cells.

(d) If the results are inconclusive, one or two blind passages shall be made using fluids from each of the original test eggs. Fluids from dead and live embryos may be pooled separately for inoculum in these passages.

(e) If hemagglutinating activity attributable to the product is observed, the serial is unsatisfactory.

[38 FR 29889, Oct. 30, 1973]

§ 113.35 Detection of viricidal activity.

The test for detection of viricidal activity provided in this section shall be conducted when such a test is prescribed in an applicable standard requirement or in the filed Outline of Production for each inactivated liquid biological product used as diluent for a dessicated live virus vaccine in a combination package.

(a) Bulk or final container samples of completed product from each serial shall be tested.

(b) The product shall be tested with each virus fraction for which it is to be used as a diluent. If the vaccine to be rehydrated contains more than one virus fraction, the test shall be conducted with each fraction after neutralization of the other fraction(s), and/or dilution of the vaccine beyond the titer range of the other fraction(s), or the test shall be conducted using representative single-fraction dessicated vaccines which are prepared by the licensee and which are licensed.

Provided, that the Deputy Administrator may authorize licensees to prepare and use unlicensed single-fraction vaccines for this purpose.

(c) Test procedure: (1) Rehydrate at least two vials of the vaccine with the liquid product under test according to label recommendations and pool the contents.

(2) Rehydrate at least two vials of the vaccine with the same volume of sterile purified water and pool the contents.

(3) Neutralize to remove other fractions, if necessary.

(4) Hold the two pools of vaccine at room temperature (20° to 25° C) for 2 hours. The holding period shall begin when rehydration is completed.

(5) Titrate the virus(es) in each pool of vaccine as provided in the filed Outline of Production or an applicable standard requirement.

(6) Compare respective titers.

(d) If the titer of the vaccine virus(es) rehydrated with the product under test is more than 0.7 $\log_{10}$ below the titer of the vaccine virus(es) rehydrated with sterile purified water, the product is unsatisfactory for use as diluent.

(e) If the product is unsatisfactory in the first test, one retest to rule out faulty techniques may be conducted using four vials of the vaccine for each pool and the acceptability of the product judged by the results of the second test.

(f) Liquid products found to be unsatisfactory for use as diluent by this test are not prohibited from release as separate licensed products if labeled as prescribed in § 112.7(h).

[44 FR 25412, May 1, 1979]

§ 113.36 Detection of pathogens by the chicken inoculation test.

The test for detection of extraneous pathogens provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) The biological product to be tested shall be prepared for use as recommended on the label, or in the case of desiccated vaccine to be used in poultry, rehydrated with sterile distilled water at the rate of 30 ml per 1,000 doses.

(b) At least 25 healthy susceptible young chickens, properly identified and obtained from the same source and hatch, shall be immunized at least 14 days prior to being put on test. The immunizing agent shall be the same as the product to be tested but from a serial previously tested and found satisfactory.

(c) At least 20 of the previously immunized birds shall be inoculated with 10 label doses of the vaccine being tested by each of the following routes: Subcutaneous, intratracheal, eye-drop, and comb scarification (1 cm^2). Twenty birds may be used for each route or combination of routes.

(d) At least five birds shall be isolated as control birds.

(e) All birds shall be observed for 21 days for signs of septicemic diseases, respiratory diseases, or other pathologic conditions.

(f) If the controls remain healthy and unfavorable reactions attributable to the product occur in the vaccinates, the serial or subserial tested is unsatisfactory. If the controls do not remain healthy or if unfavorable reactions not attributable to the product occur in the vaccinates, or both, the test shall be declared inconclusive and may be repeated: *Provided*, That, if the test is not repeated, the serial of subserial tested shall be considered unsatisfactory.

[38 FR 29889, Oct. 30, 1973, as amended at 39 FR 21042, June 18, 1974; 43 FR 7610, Feb. 24, 1978]

§ 113.37 Detection of pathogens by the chicken embryo inoculation test.

The test for detection of extraneous pathogens provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) The biological product to be tested shall be prepared for use as recommended on the label, or in the case of desiccated vaccine to be used in poultry, rehydrated with sterile distilled water at the rate of 30 ml per 1,000 doses.

(b) One volume of the prepared vaccine shall be mixed with up to nine volumes of sterile heat-inactivated specific antiserum to neutralize the vaccine virus in the product. Each lot of antiserum shall be demonstrated by virus neutralization tests not to inhibit other viruses known to be possible contaminants.

(c) After neutralization, 0.2 ml of the vaccine-serum mixture shall be inoculated into each of at least 20 fully susceptible chicken embryos.

(1) Twenty embryos, 9 to 11 days old, shall be inoculated on the chorioallantoic membrane (CAM) with 0.1 ml, and in the allantoic sac with 0.1 ml.

(2) Eggs shall be candled daily for 7 days. Deaths occurring during the first 24 hours shall be disregarded but at least 18 viable embryos shall survive 24 hours post-inoculation for a valid test. Examine all embryos and CAM's from embryos which die after the first day. When necessary, embryo subcultures shall be made to determine the cause of a death. The test shall be concluded on the seventh day post-inoculation and the surviving embryos (including CAM's) examined.

(d) If death and/or abnormality attributable to the inoculum occur, the serial is unsatisfactory: *Provided,* That, if there is a vaccine virus override, the test may be repeated, using a higher titered antiserum.

[38 FR 29889, Oct. 30, 1973, as amended at 39 FR 21042, June 18, 1974]

§ 113.38 Guinea pig safety test.

The guinea pig safety test provided in this section shall be conducted when prescribed in a Standard Requirement or approved Outline of Production for a biological product. When desiccated products are tested, final container samples of completed product prepared for administration in the manner recommended on the label shall be used. When liquid products are tested, either bulk or final container samples of completed product shall be used.

(a) Unless otherwise specified in the Standard Requirement or approved Outline of Production for the product, a 2 ml dose shall be injected either intramuscularly or subcutaneously into each of two guinea pigs and the animals observed for 7 days.

(b) If unfavorable reactions attributable to the product occur in either of the guinea pigs during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur, the test shall be declared inconclusive and may be repeated: *Provided,* That, if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

[39 FR 16857, May 10, 1974; 39 FR 20368, June 10, 1974]

§ 113.39 Cat safety tests.

The safety tests provided in this section shall be conducted when prescribed in a standard requirement or in the filed Outline of Production for a biological product recommended for use in cats.

(a) The cat safety test provided in this paragraph shall be used when the Master Seed Virus is tested for safety.

(1) The test animals shall be determined to be susceptible to the virus under test as follows:

(i) Throat swabs shall be collected from each cat and individually tested on susceptible cell cultures for the presence of the virus. Blood samples shall also be drawn and individual serum samples tested for antibody to the virus.

(ii) The cats shall be considered susceptible if swabs are negative for virus isolation and the serums are free of virus antibody at the 1:2 final dilution in a 50 percent plaque reduction test or other serum-neutralization test of equal sensitivity.

(iii) When determining susceptibility to a virus which does not lend itself to the methods in paragraphs (a)(1)(i) and (ii) of this section, a method acceptable to Veterinary Services shall be used.

(2) Each of at least 10 susceptible cats shall be administered a sample of the Master Seed Virus equivalent to the amount of virus to be used in one cat dose of the vaccine, by the method to be recommended on the label, and the cats observed each day for 14 days.

(3) If unfavorable reactions attributable to the virus occur in any of the cats during the observation period, the Master Seed Virus is unsatisfactory. If unfavorable reactions occur which are not attributable to the Master Seed Virus, the test shall be declared inconclusive and repeated: *Provided,* That, if not repeated, the Master Seed Virus shall be unsatisfactory.

(b) The cat safety test provided in this paragraph shall be used when a serial of vaccine is tested for safety before release.

(1) Each of two healthy cats shall be administered 10 cat doses by the method recommended on the label and the cats observed each day for 14 days.

(2) If unfavorable reactions attributable to the biological product occur during the observation period, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the product, the test shall be declared inconclusive and repeated: *Provided,* That, if not repeated, the serial shall be unsatisfactory.

[44 FR 58898, Oct. 12, 1979]

§ 113.40 Dog safety test.

The dog safety test provided in this section shall be conducted when prescribed in a Standard Requirement or in the filed Outline of Production for a product.

(a) *Test procedure.* (1) If vaccine is being tested, each of two puppies shall be injected with the equivalent of 10 doses of vaccine rehydrated with sterile diluent and administered in the manner recommended on the label and observed each day for 21 days.

(2) If antiserum is being tested, a dose shall be the maximum amount recommended on the label per pound body weight and each of two puppies shall be injected subcutaneously with one dose and intraveneously with one dose and observed each day for 21 days.

(b) *Interpretation.* If unfavorable reactions attributable to the product occur in either of the puppies during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur, the test shall be declared inconclusive and may be repeated: *Provided,* That, if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

[39 FR 27428, July 29, 1974]

§ 113.41 Calf safety test.

The calf safety test provided in this section shall be conducted when prescribed in a Standard Requirement or in the filed Outline of Production for a product.

(a) *Test procedure.* Each of two calves shall be injected with the equivalent of 10 doses of vaccine administered in the manner recommended on the label and observed each day for 21 days.

(b) *Interpretation.* If unfavorable reactions attributable to the product occur in either of the calves during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur, the test shall be declared inconclusive and may be repeated: *Provided,* That, if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

[39 FR 27428, July 29, 1974]

§ 113.42 Detection of lymphocytic choriomeningitis contamination.

The test for detection of lymphocytic choriomeningitis (LCM) virus provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in a filed Outline of Production. Vaccine virus may be neutralized with specific antiserum when necessary.

(a) Each of at least 10 mice obtained from a source free of LCM shall be injected in the footpad of a hindfoot with 0.02 ml of the material being tested and observed each day for 21 days.

(b) If any of the mice show swelling in the injected footpad or if more than one becomes systemically abnormal, the material being tested is unsatisfactory.

[42 FR 6794, Feb. 4, 1977]

§ 113.43 Detection of chlamydial agents.

The test for chlamydial agents provided in this section shall be conducted when such a test is prescribed in an applicable standard requirement or in a filed Outline of Production.

(a) The yolk sac of 6-day-old chicken embryos shall be injected. Three groups of 10 embryos shall be used sequentially.

(1) The inoculum for each embryo in the first group shall consist of 0.5 ml of a mixture of equal parts of the seed virus with phosphate buffered saline that may contain Streptomycin, Vancomycin, Kanamycin, or a combination thereof. Not more than 2 mg/ml of each antibiotic shall be used.

(2) On the 10th day postinoculation, the yolk sac of viable embryos shall be harvested, pooled, homogenized as a 20 percent suspension in phosphate buffered saline antibiotic diluent, and 0.5 ml of the mixture injected into the second group of chicken embryos. This process shall be repeated for the injection of the third group of embryos using the yolk sacs of viable embryos from the second group.

(3) For each of the three passages, embryo deaths occurring within 48 hours of injection shall be disregarded, except that if more than three such deaths occur at any passage, that passage shall be repeated.

(b) If one or more embryo deaths occur at any passage after 48 hours postinjection, the yolk sacs from each of the dead embryos shall be subcultured into 10 additional embryos. If one or more embryo deaths again occur due to chlamydial agents, the Master Seed Virus is unsatisfactory for use to produce vaccine.

[44 FR 58899, Oct. 12, 1979]

§ 113.44 Swine safety test.

The swine safety test provided in this section shall be conducted when prescribed in a Standard Requirement or in the filed Outline of Production for a product.

(a) *Test procedure.* (1) Inject each of two swine of the minimum age for which the product is recommended with the equivalent of two doses of bacterial vaccine or 10 doses of viral vaccine.

(2) Administer vaccine in the manner recommended on the label.

(3) Observe swine each day for 21 days.

(b) *Interpretation.* If unfavorable reactions attributable to the product occur in either of the swine during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur, the test shall be declared inconclusive and may be repeated; *Provided,* That, if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

[48 FR 33476, July 22, 1983]

§ 113.45 Sheep safety test.

The sheep safety test provided in this section shall be conducted when prescribed in a Standard Requirement or in the filed Outline of Production for a product.

(a) *Test procedure.* (1) Inject each of two sheep of the minimum age for which the product is recommended with the equivalent of two doses of bacterial vaccine or 10 doses of viral vaccine.

(2) Administer vaccine in the manner recommended on the label.

(3) Observe sheep each day for 21 days.

(b) *Interpretation.* If unfavorable reactions attributable to the product occur in either of the sheep during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur, the test shall be declared inconclusive and may be repeated; *Provided,* That, if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

[48 FR 33476, July 22, 1983]

§ 113.46 Detection of cytopathogenic and/or hemadsorbing agents.

The tests for detection of cytopathogenic and/or hemadsorbing agents provided in this section shall be conducted when prescribed in an applicable Standard Requirement or in the filed Outline of Production for a product.

(a) *Test for cytopathogenic agents.* One or more monolayers that are at least 6 cm^2 and at least 7 days from the last subculture shall be tested as provided in this paragraph.

(1) Stain each monolayer with a suitable cytological stain.

(2) Examine the entire area of each stained monolayer for evidence of inclusion bodies, abnormal number of giant cells, or other cytopathology indicative of cell abnormalities attributable to an extraneous agent.

(b) *Test for hemadsorbing agents.* One or more monolayers that are at least 6 cm^2 and at least 7 days from the last subculture shall be tested as provided in this paragraph.

(1) Wash the monolayer with several changes of phosphate buffered saline.

(2) Add an adequate volume of a 0.2 percent red blood cell suspension to uniformly cover the surface of the monolayer. Suspensions of washed guinea pig, human type "O," and chicken red blood cells shall be used. These suspensions may be mixed prior to adding to the monolayer or they may be used separately on separate monolayers.

(3) Incubate the monolayer at 4 °C for 30 minutes, wash with phosphate buffered saline, and examine for hemadsorption.

(4) If no hemadsorption is apparent, repeat step (b)(2) of this section and incubate the monolayers at 20-25 °C for 30 minutes, wash with phosphate

buffered saline, and examine again for hemadsorption. If desired, separate monolayers may be used for each incubation temperature.

(c) If specific cytopathology or hemadsorption attributable to an extraneous agent is found, the material under test is unsatisfactory and shall not be used to prepare biological products. If an extraneous agent is suspected because of cytopathology or hemadsorption and cannot be eliminated as a possibility by additional testing, the material under test is unsatisfactory.

[50 FR 441, Jan. 4, 1985]

§ 113.47 Detection of extraneous agents by the fluorescent antibody technique.

The test for detection of extraneous agents by the fluorescent antibody technique provided in this section shall be conducted when prescribed in an applicable Standard Requirement or in a filed Outline of Production for a product.

(a) Monolayers, at least 7 days after subculturing, shall be processed and stained with the appropriate antiviral fluorescein-conjugated antibody as specified in paragraph (b) of this section, except that for the detection of parvovirus, the monolayers may be stained as early as 4 days.

(1) Three groups of one or more monolayers shall be required for each specific virus prescribed in paragraph (b) of this section.

(i) At the time of the last subculturing, one group of test monolayers shall be inoculated with approximately 100-300 $FAID_{50}$ of the specific virus as positive controls.

(ii) One group of monolayers shall be the "material under test."

(iii) One group of monolayers of the same type of cell as the test monolayer shall be prepared separately with cells that have been tested as prescribed in §§ 113.51 or 113.52 (whichever is applicable) as negative controls.

(2) Each group of monolayers shall have a total area of at least 6 cm^2.

(3) Positive control monolayers may be fixed before 7 days if fluorescence is enhanced by so doing. Monolayers that are so treated shall be stained at the same time as the material under test.

(b) The antiviral fluorescein-conjugated antibody to be used shall depend on the type of cells required for testing for extraneous agents as specified in an applicable Standard Requirement or in a filed Outline of Production. Specific antiviral fluorescein-conjugated antibody shall be applied to each type of cell specified for the test in accordance with the following list. Additional antiviral fluorescein-conjugated antibody may be specified for use by the Deputy Administrator. Specific anti-viral fluorescein-conjugated antibody to be applied to cell types not listed shall be as specified by the Deputy Administrator. When a specific antiviral fluorescein-conjugated antibody is listed for application to more than one type of cell, it need only be applied to the most susceptible cell type used in propagation of the potential extraneous agent(s).

(1) Canine cells shall be tested for:

(i) Canine distemper virus;

(ii) Canine parvovirus;

(iii) Reovirus;

(iv) Rabies virus; and

(v) Bovine virus diarrhea virus.

(2) Feline cells shall be tested for:

(i) Feline panleukopenia virus;

(ii) Rabies virus;

(iii) Bovine virus diarrhea virus; and

(iv) Coronavirus.

(3) Bovine cells shall be tested for:

(i) Bovine virus diarrhea virus;

(ii) Bovine parvovirus;

(iii) Bovine adenoviruses; and

(iv) Rabies virus.

(4) Porcine cells shall be tested for:

(i) Transmissible gastroenteritis virus;

(ii) Porcine adenovirus;

(iii) Porcine parvovirus;

(iv) Bovine virus diarrhea virus; and

(v) Rabies virus.

(5) Vero cells:

(i) Reovirus (if not tested for in canine cells).

(6) Firms that do not have rabies virus on premises either for research or production purposes are exempt from having to produce positive rabies virus control monolayers. Fixed positive rabies virus control monolayers will be provided by the National Veterinary Services Laboratories.

(c) After staining, each group of monolayers shall be examined for the presence of specific fluorescence attributable to the presence of extraneous agents.

(1) If the material under test shows any evidence of specific viral fluorescence, it is unsatisfactory; *Provided*, That, if specific fluorescence attributable to virus being tested for is absent in the positive control monolayers, the test is inconclusive and may be repeated.

(2) If the fluorescence of the monolayers inoculated with the specific virus as positive controls is equivocal, or if the negative monolayers show equivocal fluorescence indicating possible viral contamination, or both, the test shall be declared inconclusive, and may be repeated; *Provided*, That, if the test is not repeated, the material under test shall be regarded as unsatisfactory.

[50 FR 441, Jan. 4, 1985]

INGREDIENT REQUIREMENTS

§ 113.50 Ingredients of biological products.

All ingredients used in a licensed biological product shall meet accepted standards of purity and quality; shall be sufficiently nontoxic so that the amount present in the recommended dose of the product shall not be toxic to the recipient; and in the combinations used shall not denature the specific substances in the product below the minimum acceptable potency within the dating period when stored at the recommended temperature.

[38 FR 29889, Oct. 30, 1973]

§ 113.51 Requirements for primary cells used for production of biologics.

Primary cells used to prepare biological products shall be derived from normal tissue of healthy animals. When prescribed in an applicable Standard Requirement or in the filed Outline of Production, each batch of primary cells used to prepare a biological product shall be tested as prescribed in this section. A batch of primary cells found unsatisfactory by any prescribed test shall not be used. A serial of biological product shall not be released if produced from primary cells that are found unsatisfactory by any prescribed test.

(a) Final container samples of completed product or samples of the final pool of harvested material or samples of each subculture of cells used to prepare the biological product shall be shown free of mycoplasma as prescribed in § 113.28. The sample for testing shall consist of at least 75 cm^2 of actively growing cells or the equivalent in harvest fluids; *Provided*, That all sources of cells in the batch of primary cells are represented.

(b) Final container samples of completed product or samples of the final pool of harvested material or samples of each subculture of cells used to prepare the biological product shall be shown free of bacteria and fungi as prescribed in § 113.26 or § 113.27 (whichever is applicable).

(c) A monolayer at least 75 cm^2 from each batch of primary cells or each subculture of primary cells used to prepare a biological product shall be shown free of extraneous agents as prescribed in this paragraph.

(1) The test monolayer shall be maintained using the medium (with additives) and under conditions similar to those used to prepare biological products.

(i) Monolayers of avian origin shall be maintained for at least 14 days and shall be subcultured at least once during the maintenance period. All but the last subculture shall result in a new monolayer of at least 75 cm^2. The last subculture shall meet the minimum area requirement specified in §§ 113.46 and 113.47.

(ii) Monolayers not of avian origin shall be maintained for at least 28 days and shall be subcultured at least twice during the maintenance period. All but the last subculture shall result in a new monolayer of at least 75 cm^2. The last subculture shall meet the minimum area requirement specified in §§ 113.46 and 113.47.

(2) Monolayers shall be examined regularly throughout the required maintenance period for evidence of the presence of cytopathogenic agents. If evidence of a cytopathogenic agent is found, the batch of primary cells is unsatifactory.

(3) At the conclusion of the required maintenance period, monolayers shall be tested for:

(i) Cytopathogenic and/or hemadsorbing agents as prescribed in § 113.46;

(ii) Extraneous agents by the fluorescent antibody technique as prescribed in § 113.47.

[50 FR 442, Jan. 4, 1985]

§ 113.52 Requirements for cell lines used for production of biologics.

When prescribed in an applicable Standard Requirement or in a filed Outline of Production each cell line used to prepare a biological product shall be tested as prescribed in this section. A cell line found unsatisfactory by any prescribed test shall not be used. A serial of biological product shall not be released if produced from a cell line that is found unsatisfactory by any prescribed test.

(a) *General requirements.* (1) A complete record of the cell line shall be kept, such as, but not limited to, the source, passage history, and medium used for propagation.

(2) A Master Cell Stock (MCS) shall be established at a specified passage level for each cell line. The passage level and identity of the MCS and the highest passage level (MCS + n) intended for use in the preparation of a biological product shall be specified in the Outline of Production for the product.

(3) Sufficient 1.0 ml or larger aliquots of MCS and MCS + n shall be prepared, kept in a frozen state, and made available to Veterinary Services (VS) upon request for performing the tests prescribed in this section.

(4) Each lot of cells shall be monitored for the characteristics determined to be normal for the cell line, such as, but not limited to, microscopic appearance, growth rate, acid production, or other observable features.

(b) The MCS shall be shown to be of the same species of origin as that reported in paragraph (a)(1) of this section by the following method:

(1) At least four monolayers with a total area of at least 6 cm^2 shall be grown to at least 80 percent confluency.

(2) The monolayers shall be removed from their media, processed, stained, and examined.

(i) At least two monolayers shall be stained with an antispecies fluorescein-conjugated antibody unrelated to the species of origin of the MCS.

(ii) At least two monolayers shall be stained with an antispecies fluorescein-conjugated antibody specific to the species of origin of the MCS.

(iii) All monolayers shall be examined for evidence of specific fluorescence.

(3) If specific fluorescence is not found in the monolayers stained with the conjugate specific to the species of origin of the MCS, the cell line is unsatisfactory and shall not be used for vaccine production.

(4) If nonspecific fluorescence is found in the monolayers stained with conjugate from an unrelated species of origin or other results make the test results equivocal, the procedure shall be repeated until either specific fluorescence is found only in the monolayers stained with conjugate specific to the species of origin of the MCS and not in the control monolayers or specific fluorescence cannot be identified and the MCS is declared unsatisfactory.

(5) Alternate tests to determine the species of origin of the MCS may be used if approved by VS.

(c) The MCS and either each subculture of cells used to prepare a biological product or the final pool of harvested material (with or without the stabilizer) or final container samples of completed product for each serial of such product shall be shown to be free of mycoplasma as prescribed in § 113.28. The sample for testing shall consist of at least 75 cm^2 of actively growing cells or the equivalent, in harvest fluids. The cells shall represent all sources of cells in the batch.

(d) The MCS and either each subculture used to prepare a biological product or the final pool of harvested material for each serial of such product or final container samples of completed product for each serial of such product shall be tested for bacteria and fungi as prescribed in § 113.26 or § 113.27 (whichever is applicable). If bacteria or fungi are found in the

MCS, the MCS shall not be used. If bacteria or fungi are found in a subculture, the subculture shall not be used.

(e) A monolayer at least 75 cm² from each MCS shall be shown free of extraneous agents as prescribed in this paragraph.

(1) The test monolayer shall be maintained for at least 21 days using the medium (with additives) intended for growth and maintenance and under conditions similar to those used to prepare biological products.

(2) Cells shall be subcultured at least two times during the maintenance period. All but the last subculture shall result in at least one new monolayer of at least 75 cm². The last subculture shall meet the minimum area requirement specified in §§ 113.46 and 113.47 and paragraph (f) of this section.

(3) Monolayers shall be examined regularly throughout the 21-day maintenance period for evidence of the presence of cytopathogenic agents. If evidence of a cytopathogenic agent is found, the MCS is unsatisfactory.

(4) At the conclusion of the 21-day maintenance period, monolayers shall be tested for:

(i) Cytopathogenic and/or hemadsorbing agents as prescribed in § 113.46; and

(ii) Extraneous agents by the fluorescent antibody technique as prescribed in § 113.47.

(f) At the conclusion of the 21-day maintenance period provided in paragraph (e) of this section, at least one monolayer of at least 75 cm² shall also be shown free of extraneous agents as prescribed in this paragraph.

(1) Alternately freeze and thaw the monolayer(s) three times. Centrifuge the disrupted cells at no greater than 2,000 x g for no more than 15 minutes to remove cellular debris. Divide the supernatant into equal aliquots and dispense 1.0 ml onto each of at least one monolayer (at least 75 cm²) of:

(i) Vero (African green monkey kidney) cell line;

(ii) Embryonic cells, neonatal cells, or a cell line of the same species of origin as the MCS if different than provided in paragraph (f)(1)(i) of this section;

(iii) Embryonic cells, neonatal cells, or a cell line of the species for which the vaccine is recommended if different than provided in paragraph (f)(1)(ii) of this section; and

(iv) Embryonic cells, neonatal cells, or a cell line of bovine origin if not specified in paragraphs (f)(1) (ii), and (iii) of this section.

(2) The monolayers of cells specified in paragraphs (f)(1) (i), (ii), (iii), and (iv) of this section shall be maintained for at least 14 days after inoculation with the aliquot of disrupted MCS. Monolayers shall be subcultured at least once during the maintenance period. All but the last subculture shall result in a new monolayer of at least 75 cm². The last subculture shall meet the minimum area requirement specified in §§ 113.46 and 113.47.

(3) Monolayers shall be examined regularly throughout the 14-day maintenance period for evidence of the presence of cytopathogenic agents. If evidence of a cytopathogenic agent is found, the MCS is unsatisfactory.

(4) At the conclusion of the 14-day maintenance period, monolayers shall be tested for:

(i) Cytopathogenic and/or hemadsorbing agents as prescribed in § 113.46; and

(ii) Extraneous agents by the fluorescent antibody technique as prescribed in § 113.47.

(g) The karyology of cells lines used in the production of biologics shall be examined as follows. A minimum of 50 mitotic cells shall be examined at both the MCS and MCS+n. The modal number in the MSC+n shall not exceed plus or minus 15 percent of the modal number of the MCS. Any marker chromosomes present in the MSC shall persist at the MCS+n. If the modal number exceeds the limits and/or the marker chromosomes do not persist (through the MCS+n passage level), the cell line shall not be used for vaccine production.

(h) If direct or indirect evidence exists that a cell line which is intended for use in the preparation of a vaccine may induce malignacies in the species for which the product is intended, that cell line shall be tested for tumorigenicity/oncogenicity by a method acceptable to VS.

[50 FR 442, Jan. 4, 1985; 50 FR 3316, Jan. 24, 1985]

§ 113.53 Requirements for ingredients of animal origin used for production of biologics.

Each lot of ingredient of animal origin which is not subjected to heat sterilization or other sterilization methods acceptable to Veterinary Service (VS), such as, but not limited to serum and albumin, used to prepare a biological product shall be tested as prescribed in this section by the licensee or a laboratory acceptable to VS. Results of all tests shall be recorded by the testing laboratory and made a part of the licensee's records. A lot of ingredient found unsatisfactory by any prescribed test shall not be used to prepare a biological product. A serial of biological product shall not be released if produced using an ingredient that is found unsatisfactory by any prescribed test.

(a) Samples of each lot of ingredient of animal origin which is not subjected to heat sterilization, used to prepare a biological product shall be shown free of mycoplasma by the method prescribed in § 113.28.

(b) Samples of each lot of ingredient or animal origin which is not subjected to heat sterilization of other sterilization methods acceptable to VS used to prepare a biological product shall be shown free of bacteria and fungi as prescribed in § 113.26.

(c) Samples of each lot of ingredient of animal origin, except porcine trypsin, which is not subjected to heat sterilization or other viricidal procedure acceptable to VS used in the preparation of biological products shall be tested as prescribed in this paragraph;

(1) Monolayers at least 75 cm^2 of Vero (African green monkey kidney) cell line and of primary cells or a cell line of the same species of origin as the ingredient shall be used in the test. Cell lines used shall have been found satisfactory when tested as prescribed in § 113.52 and primary cells used shall have been found satisfactory when tested as prescribed in § 113.51.

(2) At least 3.75 ml or 15 percent of the ingredient shall be used in the growth medium for the preparation of at least 75 cm^2 test monolayers. The ingredient shall also be used in the growth medium when monolayers are subcultured. If the ingredient being tested is cytotoxic when tested in this manner, other procedures may be used if approved by VS.

(3) The test monolayers shall be maintained for at least 21 days.

(4) Cells shall be subcultured at least two times during the maintenance period. All but the last subculture shall result in at least one new monolayer of at least 75 cm^2. The last subculture shall meet the minimum area requirements specified in §§ 113.46 and 113.47.

(5) Monolayers shall be examined regularly throughout the 21-day maintenance period for evidence of cytopathogenic agents. If evidence of a cytopathogenic agent is found, the ingredient is unsatisfactory.

(6) At the conclusion of the 21-day maintenance period, monolayers shall be tested for:

(i) Cytopathogenic and/or hemadsorbing agents as prescribed in § 113.46; and

(ii) Extraneous agents by the fluorescent antibody technique as prescribed in § 113.47.

(d) Each lot of porcine trypsin which has not been treated to inactivate porcine parvovirus (PPV) in a manner acceptable to VS shall be tested for PPV as prescribed in this paragraph.

(1) Not less than 5.0 grams of trypsin shall be dissolved in a volume of suitable diluent sufficient to fill a centrifuge angle head. After centrifuging for 1 hour at 80,000 x g, the pellet material shall be reconstituted in distilled water and inoculated into a flask containing 75 cm^2 of a 30 to 50 percent confluent monolayer culture of primary porcine cells or a porcine cell line of proven equal PPV susceptibility. An additional flask of cells shall be held as a negative control.

(2) The test and control monolayers shall be maintained for at least 14 days and subcultured at least once during the maintenance period.

(3) At the end of the 14-day maintenance period, and 4 to 7 days after the last subculturing, monolayers shall be tested for the presence of porcine par-

vovirus by the fluorescent antibody technique as prescribed in § 113.47(c).

(e) A sample of serum from each donor horse used to produce a lot of equine serum used in the preparation of biological products recommended for use in horses shall be tested at a laboratory approved by Veterinary Services using the Coggins test for equine infectious anemia antibodies. If antibodies to equine infectious anemia are found, the lot of serum is unsatisfactory.

[50 FR 442, Jan. 4, 1985; 50 FR 3316, Jan. 24, 1985]

§ 113.54 Sterile diluent.

Sterile Diluent shall be supplied in a final container by the licensee when such diluent is required for rehydration or dilution of the vaccine.

(a) Sterile Diluent may be distilled or deionized water or it may be a special liquid solution formulated in accordance with an acceptable outline on file with Veterinary Services.

(b) Each quantity prepared at one time in a single container and bottled into final containers shall be designated as a serial. Each serial shall be given a number which shall be used in records, test reports, and on the final container label.

(c) Final container samples from each serial shall be tested for bacteria and fungi in accordance with the test provided in § 113.26. Any serial found to be unsatisfactory shall not be released.

[39 FR 27428, July 29, 1974]

§ 113.55 Detection of extraneous agents in Master Seed Virus.

Unless otherwise prescribed in a Standard Requirement or in a filed Outline of Production, each Master Seed Virus (MSV) shall be tested as prescribed in this section. A MSV found unsatisfactory by any prescribed test shall not be used. A serial of biological product shall not be released if produced from a MSV that is found unsatisfactory by any prescribed test.

(a) At least a 1.0 ml aliquot per cell culture of MSV shall be dispensed onto monolayers (at least 75 cm^2 in area) of:

(1) Vero (African green monkey kidney) cell line;

(2) Embryonic cells, neonatal cells, or a cell line of the species for which the vaccine is recommended; and

(3) Embroynic cells, neonatal cells, or a cell line of the species of cells in which the MSV is presently being propagated if different than prescribed in paragraphs (a)(1) and (a)(2) of this section. Cell lines used shall have been found satisfactory when tested as prescribed in § 113.52 and primary cells used shall have been found satisfactory when tested as prescribed in § 113.51. If the MSV is cytopathic for or causes hemadsorption in the cells in which it is to be tested, the MSV shall be neutralized with monospecific antiserum supplied or approved by Veterinary Services (VS) or counteracted by a method approved by VS.

(b) At least one monolayer of each cell type used in the test shall be maintained as an uninoculated control.

(c) Each monolayer shall be maintained at least 14 days.

(d) Cells shall be subcultured at least once during the maintenance period. All but the last subculture shall result in at least one new monolayer at least 75 cm^2. The last subculture shall meet the minimum area requirement specified in §§ 113.46 and 113.47.

(e) Monolayers shall be examined regularly throughout the 14-day maintenance period for evidence of cytopathogenic agents. If evidence of a cytopathogenic agent is found, the MSV is unsatisfactory.

(f) At the conclusion of the 14-day maintenance period, monolayers shall be tested for:

(1) Cytopathogenic and/or hemadsorbing agents as prescribed in § 113.46;

(2) Extraneous agents by the fluorescent antibody technique as prescribed in § 113.47.

[50 FR 444, Jan. 4, 1985]

LIVE BACTERIAL VACCINES

§ 113.64 General requirements for live bacterial vaccines.

When prescribed in an applicable Standard Requirement or in the filed Outline of Production, a live bacterial vaccine shall meet the requirements in this section.

(a) *Purity test.* Final container samples of completed product from each serial and subserial, and samples of each lot of Master Seed Bacteria shall be tested for the presence of extraneous viable bacteria and fungi in accordance with the test provided in § 113.27(b).

(b) *Safety tests.* (1) Samples of completed product from each serial or first subserial and samples of each lot of Master Seed Bacteria shall be tested for safety in young adult mice in accordance with the test provided in § 113.33(b) unless:

(i) The bacteria or agents in the vaccine are inherently lethal for mice.

(ii) The vaccine is recommended for poultry.

(2) Samples of completed product from each serial or first subserial of live bacterial vaccine shall be tested for safety in one of the species for which the product is recommended as follows:

(i) Live bacterial vaccine recommended for use in dogs shall be tested as provided in § 113.40, except that dogs shall be injected with the equivalent of two doses of vaccine administered as recommended on the label.

(ii) Live bacterial vaccine recommended for use in cattle shall be tested as provided in § 113.41, except that calves shall be injected with the equivalent of two doses of vaccine administered as recommended on the label.

(iii) Live bacterial vaccine recommended for use in sheep shall be tested as provided in § 113.45.

(iv) Live bacterial vaccine recommended for use in swine shall be tested as provided in § 113.44.

(c) *Identity test.* At least one of the identity tests provided in this paragraph shall be conducted for the Master Seed Bacteria and final container samples from each serial or first subserial of completed biological product. A known positive control (reference) provided or approved by Veterinary Services shall be included in such tests.

(1) *Fluorescent antibody test.* The direct fluorescent antibody staining technique shall be conducted using suitable smears of the vaccine bacteria. Fluorescence typical for the bacteria concerned shall be demonstrated. Fluorescence shall not occur in control smears treated with specific antiserum.

(2) *Tube agglutination test.* A tube agglutination test shall be conducted with a suitable suspension of the vaccine bacteria using the constant antigen decreasing serum method with specific antiserum. Agglutination typical for the bacteria shall be demonstrated. Agglutination shall not occur with negative serum used as a control in this test.

(3) *Slide agglutination test.* The rapid plate (slide) agglutination test shall be conducted with suitable suspensions of the vaccine bacteria using the hanging drop, slide or plate method, with specific antiserum. Agglutination typical for the bacteria shall be demonstrated by microscopic or macroscopic observation. Agglutination shall not occur with negative serum used as a control in this test.

(4) *Characterization tests.* Applicable biochemical and cultural characteristics shall be demonstrated as specified in the filed Outline of Production.

(d) *Ingredient requirements.* Ingredients used for the growth and preparation of Master Seed Bacteria and of live bacterial vaccine shall meet the requirements provided in § 113.50. Ingredients of animal origin shall meet the applicable requirements provided in § 113.53.

(e) *Moisture content.* (1) The maximum percent moisture in desiccated vaccines shall be stated in the filed Outline of Production and shall be established by the licensee as follows:

(i) *Prelicensing.* Data obtained by conducting accelerated stability tests and bacterial counts shall be acceptable on a temporary basis.

(ii) *Licensed products.* Data shall be obtained by determining the percent moisture and bacterial count at release and expiration on a minimum of 10 consecutive released serials.

(2) Final container samples of completed product from each serial and subserial shall be tested for moisture content in accordance with the test provided in § 113.29.

[48 FR 33476, July 22, 1983]

§ 113.65 Brucella Abortus Vaccine.

Brucella Abortus Vaccine shall be prepared as a desiccated live culture bacterial vaccine from smooth colonial forms of the *Brucella abortus* organism, identified as Strain 19. Each serial and subserial shall be tested for purity, potency, and moisture content. A serial or subserial found unsatisfactory by a prescribed test shall not be released.

(a) *Purity tests.* Each serial and subserial shall be tested for purity as provided in this paragraph.

(1) Macroscopic and microscopic examination shall be made on bulk samples from production containers. If organisms not typical of *Brucella abortus* organisms are evident, the serial or subserial is unsatisfactory.

(2) Two final container vials of completed product shall be tested by inoculating one tube of Dextrose Andrades broth with gas tube and one tube of thioglycollate broth from each vial. The inoculated media shall be incubated at 35 to 37 °C for 96 hours. If growth not typical of *Brucella abortus* organisms is evident, the serial or subserial is unsatisfactory.

(3) Bacterial dissociation test. Final container samples of completed product from each serial and subserial shall be tested for bacterial dissociation. Smooth colonies are the desired form. Rough colonies are undesirable terminal dissociation forms. Intermediate and intermediate-to-rough are also undesirable.

(i) The sample container shall be rehydrated and streaked on one potato agar plate in such a manner as to produce confluent colonies. Artificial reflected light shall be used so that the rays pass through the plate at a 45° angle.

(ii) If the vaccine contains more than 5 percent rough colonies or more than 15 percent total undesirable colonies, the serial or subserial is unsatisfactory. If organisms or growth not characteristic of *Brucella abortus* are found, the serial or subserial is unsatisfactory. The test may be repeated one time using double the number of samples: *Provided,* That, if the test is not repeated, the serial or subserial is unsatisfactory.

(b) *Bacterial count requirements for reduced dose vaccine.* Each serial and each subserial shall be tested for potency.

(1) Two final container vials of completed product shall be tested for the number of viable organisms per dose of rehydrated vaccine. A bacterial count per vial shall be made on tryptose agar plates from suitable dilutions using 1 percent peptone as a diluent. The inoculated media shall be incubated at 35 to 37 °C for 96 hours.

(2) If the average count of the two final container samples of freshly prepared vaccine contains less than 3.0 or more than 10.0 billion organisms per dose, the serial or subserial is unsatisfactory.

(3) If the average count on the initial test is less than the minimum or greater than the maximum required in paragraph (b)(2) of this section, the serial or subserial may be retested one time using four additional final container vials. The average count of the retest is determined. If the average count of the four vials retested is less than the required minimum or greater than the required maximum, the serial or subserial is unsatisfactory. If the average count of the four vials retested is within the required limits described in paragraph (b)(2) of this section, the following shall apply:

(i) If the average count obtained in the initial test is less than one-third or more than three times the average count obtained on the retest, the average count of the initial test shall be considered the result of test system error and the serial or subserial is satisfactory.

(ii) If the average count obtained in the initial test is one-third or more than the average retest count or three times or less than the average retest count, a new average count shall be determined from the counts of all six vials. If the new average is less than the minimum or greater than the maximum required in paragraph (b)(2) of this section, the serial or subserial is unsatisfactory.

(4) If tested at any time within the expiration period, each dose of rehydrated vaccine must contain at least 3.0 billion viable organisms per dose.

(c) *Bacterial count requirements for standard vaccine.* Each serial and subserial shall be tested for potency.

(1) Two final container samples shall be tested for the number of viable organisms per milliliter of rehydrated vaccine. One bacterial count per vial shall be made on tryptose agar plates from suitable dilutions using 1 percent peptone as a diluent. The inoculated media shall be incubated at 35 to 37 °C for 96 hours.

(2) If the average count of the two final container samples of freshly prepared vaccine does not contain at least 10 billion viable organisms per milliliter, the serial or subserial is unsatisfactory.

(3) If the initial bacterial count is less than 10 billion organisms per milliliter, the serial or subserial may be retested one time using four samples. If the average count of the four vials retested is less than the required minimum, the serial or subserial is unsatisfactory.

(4) If tested at any time within the expiration period, each milliliter of rehydrated vaccine does not contain at least 5 billion viable organisms per milliliter, the serial or subserial is unsatisfactory.

[39 FR 16857, May 10, 1974. Redesignated at 39 FR 25463, July 11, 1974, and amended at 40 FR 758, Jan. 3, 1975; 50 FR 23794, Jan. 6, 1985]

§ 113.66 Anthrax Spore Vaccine—Nonencapsulated.

Anthrax Spore Vaccine—Nonencapsulated shall be a live spore suspension prepared from nonencapsulated variants of *Bacillus anthracis.* Only Master Seed which has been established as pure, safe, and immunogenic shall be used for production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.64 and the requirements in this section.

(b) Each lot of Master Seed shall be tested for immunogenicity as follows:

(1) Forty-two susceptible guinea pigs from the same source each weighing 400 to 500 grams, shall be used as test animals (30 vaccinates and 12 controls).

(2) An arithmetic mean spore count of vaccine produced from the highest passage of the Master Seed shall be established before the immunogenicity test is conducted. The guinea pigs used as vaccinates shall be injected as recommended on the label with a predetermined number of vaccine spores. To confirm the dosage, five replicate spore counts shall be conducted on a sample of the vaccine dilution used.

(3) Fourteen to fifteen days postvaccination the vaccinates and controls shall each be challenged with not less than 4,500 guinea pig LD_{50} of a virulent suspension of *Bacillus anthracis* furnished or approved by Veterinary Services and observed for 10 days.

(4) If at least 10 of the 12 controls do not die from *Bacillus anthracis* within the 10-day postchallenge observation period the test is invalid and may be repeated.

(5) If at least 27 of 30 of the vaccinates do not survive the 10-day postchallenge observation period, the Master Seed is unsatisfactory.

(6) The Master Seed shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. The vaccinates and controls must meet the criteria prescribed in paragraphs (b)(4) and (b)(5) of this section.

(7) An Outline of Production change shall be made before authority for use of a new lot of Master Seed shall be granted by Veterinary Services.

(c) *Test Requirements for Release.* Each serial and subserial shall meet the applicable general requirements prescribed in 9 CFR 113.64 and the requirements in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety test.* Samples of completed product from each serial or first subserial shall be tested for safety in

sheep or goats by the methods described in 9 CFR 113.45(a).

(2) *Spore Count Requirements.* Final container samples of completed product shall be tested for spore count. Samples shall be diluted in tenfold steps. Each dilution expected to yield 30 to 300 colonies per plate shall be plated in triplicate on tryptose agar, inverted, and incubated at 35 to 70° C for 24 hours to 28 hours. Each plate having uniformly distributed colonies shall be counted and an average count determined. To be eligible for release, each serial and each subserial shall have a spore count sufficiently greater than that of the vaccine used in the immunogenicity test to assure that when tested at any time within the expiration period, each serial and subserial shall have a spore count of at least twice that used in the immunogenicity test but not less than 2,000,000 spores per dose.

[50 FR 23794, June 6, 1985]

§ 113.67 Erysipelothrix Rhusiopathiae Vaccine.

Erysipelothrix Rhusiopathiae Vaccine shall be prepared as a desiccated live culture of an avirulent or modified strain of *Erysipelothrix rhusiopathiae.* Only Master Seed which has been established as pure, safe, and immunogenic shall be used for vaccine production.

(a) The Master Seed shall meet the applicable requirements prescribed in § 113.64 and the requirements in this section.

(b) Each lot of Master Seed used for vaccine production shall be tested for immunogenicity. The selected bacterial count from the lot of Master Seed shall be established as follows:

(1) Thirty *Erysipelothrix rhusiopathiae* susceptible swine shall be used as test animals (20 vaccinates and 10 controls) for each route of administration recommended on the label.

(2) An arithmetic mean count of the colony forming units from vaccine produced from the highest passage of the Master Seed shall be established before the immunogenicity test is conducted. The 20 swine to be used as vaccinates shall be injected as recommened on the label with a predetermined quantity of vaccine bacteria. The 10 control swine shall be held separately from the vaccinates. To confirm the dosage calculation, an arithmetic mean count shall be established by conducting five replicate titrations on a sample of the bacterial vaccine dilution used. Only plates containing between 30 and 300 colonies shall be considered in a valid test.

(3) The vaccinates and controls shall be examined and their average body temperature determined prior to challenge. Fourteen to twenty-one days postvaccination, the vaccinates and controls shall be challenged with a virulent *Erysipelothrix rhusiopathiae* culture and observed for 7 days. The challenge culture and instructions for preparation and use shall be obtained from Veterinary Services.

(4) A satisfactory challenge shall be evidenced in the controls by a high body temperature or clinical signs including, but not limited to acute illness with hyperemia of the abdomen and ears, possibly terminating in sudden death; moribundity, with or without metastatic skin lesions; depression with anorexia, stiffness, and/or joint involvement; or any combination of these symptoms and lesions.

(5) If at least 80 percent of the controls do not show characteristic signs during the observation period including, but not limited to a body temperature of 105.6 °F or higher on at least 2 consecutive days, the test shall be considered inconclusive: *Provided,* That control pigs which meet the criteria requirements for susceptibility except for high body temperature shall be considered susceptible if sacrificed and organisms identified as *Erysipelothrix rhusiopathiae* can be isolated from the blood, spleen, or other organs.

(6) To demonstrate immunity after challenge, the vaccinates shall remain free of clinical signs and the body temperature shall not exceed 104.6 °F on 2 or more consecutive days. If at least 90 percent of the vaccinates do not remain free from clinical signs and high body temperature throughout the observation period, the Master Seed is unsatisfactory.

(7) The Master Seed shall be retested for immunogenicity in 3 years. Only five vaccinates and five controls need to be used in the retest: *Provid-*

ed, That at least four of five vaccinates and four of the five controls shall meet the criteria prescribed in paragraphs (b)(5) and (b)(6) of this section.

(8) An Outline of Production change shall be made before authority for use of a new Master Seed shall be granted by Veterinary Services.

(c) *Test requirements for release.* Each serial and subserial shall meet the applicable requirements in § 113.64 and the requirements in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety test.* Samples of completed product from each serial or first subserial shall be tested for safety in young adult mice as prescribed in § 113.33(b) and in swine as prescribed in § 113.44.

(2) *Bacterial count requirements.* Final container samples of completed product from each serial and each subserial shall be tested for bacterial count using the method used in paragraph (b)(2) of this section. Two replicate titrations shall be conducted on each sample. To be eligible for release, each serial and subserial shall have a bacterial count sufficiently greater than that of the vaccine used in the immunogenicity test to assure that, when tested at any time within the expiration period, each serial and subserial shall have a bacterial count two times greater than that used in such immunogenicity test.

[50 FR 23795, June 6, 1985]

INACTIVATED BACTERIAL PRODUCTS

§ 113.85 Bacterins, toxoids, bacterin-toxoids, and bacterial extracts.

Basic requirements for bacterins, toxoids, bacterian-toxoids, and bacterial extracts are provided in this section.

(a) A *bacterin* shall be an antigenic suspension of organisms, representing a whole culture or a concentrate thereof, with or without the unevaluated growth products, which has been inactivated as demonstrated by acceptable tests written into the filed Outline of Production for the product.

(b) A *toxoid* shall be a sterile, antigenic filtrate resulting from growth of bacterial organisms in a cultural medium which has had the bacterial cells removed, has been inactivated without appreciable loss of antigenic value as measured by suitable tests, and which is nontoxic as demonstrated by acceptable tests written into the filed Outline of Production.

(c) A *bacterin-toxoid* shall be:

(1) A suspension of organisms, representing a whole culture or a concentrate thereof, with the toxic growth products from the culture which has been inactivated without appreciable loss of antigenic value as measured by suitable tests, the inactivation of organisms and toxins being demonstrated by acceptable tests written into the filed Outline of Production: *Provided*, That, it shall contain cellular antigens and shall stimulate the development of antitoxin; or

(2) A combination product combining one or more toxoids or bacterin-toxoids with one or more bacterins or one or more bacterin-toxoids.

(d) A *bacterial extract* shall be the sterile, nontoxic, antigenic derivatives extracted from bacterial organisms or from culture medium in which bacterial organisms have grown.

(e) Only serials tested for viricidal activity in accordance with the test provided in § 113.35 and found satisfactory by such test shall be packaged as diluent for desiccated fractions in combination packages.

(f) If formaldehyde is used as the inactivating agent and the serial has not been found satisfactory by the viricidal activity test, bulk or final container samples of completed product from each serial shall be tested for residual free formaldehyde content using the Basic Fuchsin Test.

(1) The residual free formaldehyde content of biological products containing Clostridial antigens shall not exceed the equivalent of 0.5 percent formaldehyde solution (1,850 parts per million formaldehyde.)

(2) The residual free formaldehyde content of bacterins, bacterin-toxoids, and toxoids other than those containing Clostridial antigens, shall not exceed the equivalent of 0.2 percent formaldehyde solution (740 parts per million formaldehyde.)

[39 FR 16862, May 10, 1974, as amended at 49 FR 22625, May 31, 1984]

§ 113.86 Leptospira Pomona Bacterin.

Leptospira Pomona Bacterin shall be produced from a culture of *Leptospira pomona* which has been inactivated and is nontoxic. Each serial of biological product containing *Leptospira pomona* fraction shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product shall be diluted with physiological saline so that each 0.25 ml contains not more than 1/800th of the dose recommended on the label and shall be tested for potency, using the two-stage test provided in this paragraph.

(1) *Vaccinates.* Inject each of at least 10 but not more than 12 young adult hamsters, each weighing 50 to 90 grams, with 0.25 ml of the diluted bacterin either subcutaneously or intramuscularly, in accordance with the label recommendations for use.

(2) *Controls.* Retain at least 10 but not more than 12 additional hamsters from the same group as unvaccinated controls.

(3) *Challenge.* From 14 to 18 days postvaccination, challenge each of 10 vaccinates and each of 10 controls intraperitoneally with a suspension of virulent *Leptospira pomona* organisms, using a dose of 10-10,000 hamster LD_{50} as determined by titration.

(4) *Post-challenge period.* Observe the vaccinates and controls for 14 days post-challenge and record all deaths. If eight or more controls die of leptospirosis, the test is valid and the results shall be evaluated according to the following table:

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total dead hamsters for satisfactory serial	Cumulative total dead hamsters for unsatisfactory serial
1	10	10	2 or less	5 or more.
2	10	20	5 or less	6 or more.

(5) If three or four vaccinates die in the first stage, the second stage shall be conducted in a manner identical to the first stage.

(6) If the second stage is used, each serial shall be evaluated according to the second part of the table. On the basis of cumulative results, each serial shall either pass or fail.

[39 FR 16862, May 10, 1974, as amended at 40 FR 20067, May 8, 1975; 45 FR 40100, June 13, 1980]

§ 113.87 Leptospira Icterohaemorrhagiae Bacterin.

Leptospira Icterohaemorrhagiae Bacterin shall be produced from a culture of *Leptospira icterohaemorrhagiae* which has been inactivated and is nontoxic. Each serial of biological product containing *Leptospira icterohaemorrhagiae* fraction shall meet the applicable requirements in § 113.85 and be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product shall be diluted with physiological saline so that each 0.25 ml contains not more than 1/80th of the dose recommended on the label and shall be tested for potency, using the two-stage test provided in this paragraph.

(1) *Vaccinates.* Inject each of at least 10 but not more than 12 young adult hamsters, each weighing 50 to 90 grams, with 0.25 ml of the diluted bacterin either subcutaneously or intra-

muscularly, in accordance with the label recommendations for use.

(2) *Controls.* Retain at least 10 but not more than 12 additional hamsters from the same group as unvaccinated controls.

(3) *Challenge.* From 14 to 18 days postvaccination, challenge each of 10 vaccinates and each of 10 controls intraperitoneally with a suspension of virulent *Leptospira icterohaemorrhagiae* organisms, using a dose of 10-10,000 hamster LD_{50} as determined by titration.

(4) *Post-challenge period.* Observe the vaccinates and controls for 14 days post-challenge and record all deaths. If eight or more controls die from leptospirosis, the test is valid and the results shall be evaluated according to the following table:

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total dead hamsters for satisfactory serial	Cumulative total dead hamsters for unsatisfactory serial
1	10	10	2 or less	5 or more.
2	10	20	5 or less	6 or more.

(5) If three or four vaccinates die in the first stage, the second stage shall be used. The second stage shall be conducted in a manner identical to the first stage.

(6) If the second stage is used, each serial shall be evaluated according to the second part of the table. On the basis of cumulative results, each serial shall either pass or fail.

[39 FR 16862, May 10, 1974, as amended at 45 FR 40100, June 13, 1980]

§ 113.88 Leptospira Canicola Bacterin.

Leptospira Canicola Bacterin shall be produced from a culture of *Leptospira canicola* which has been inactivated and is nontoxic. Each serial of biological product containing *Leptospira canicola* fraction shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. Serials found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product shall be diluted with physiological saline so that each 0.25 ml contains not more than 1/80th of the dose recommended on the label and shall be tested for potency, using the two-stage test provided in this paragraph.

(1) *Vaccinates.* Inject each of at least 10 but not more than 12 young adult hamsters, each weighing 50 to 90 grams, with 0.25 ml of the diluted bacterin either subcutaneously or intramuscularly, in accordance with the label recommendations for use.

(2) *Controls.* Retain at least 10 but not more than 12 additional hamsters from the same group as unvaccinated controls.

(3) *Challenge.* From 14 to 18 days postvaccination, challenge each of 10 vaccinates and each of 10 controls intraperitoneally with a suspension of virulent *Leptospira canicola* organisms, using a dose of 10-10,000 hamster LD_{50} as determined by titration.

(4) *Post-challenge period.* Observe the vaccinates and controls for 14 days post-challenge and record all deaths. If eight or more controls die from leptospirosis, test is valid and the results shall be evaluated according to the following table:

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total dead hamsters for satisfactory serial	Cumulative total dead hamsters for unsatisfactory serial
1	10	10	2 or less	5 or more.
2	10	20	5 or less	6 or more.

(5) If three or four vaccinates die in the first stage, the second stage shall be used. The second stage shall be conducted in a manner identical to the first stage.

(6) If the second stage is used, each serial shall be evaluated according to the second part of the table. On the

basis of cumulative results, each serial shall either pass or fail.

[39 FR 16862, May 10, 1974, as amended at 45 FR 40100, June 13, 1980]

§ 113.89 Leptospira Grippotyphosa Bacterin.

Leptospira Grippotyphosa Bacterin shall be produced from a culture of *Leptospira grippotyphosa* which has been inactivated and is nontoxic. Each serial of biological product containing *Leptospira grippotyphosa* fraction shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product shall be diluted with physiological saline so that each 0.25 ml contains not more than 1/800th of the dose recommended on the label and shall be tested for potency, using the two-stage test provided in this paragraph.

(1) *Vaccinates.* Inject each of at least 10 but not more than 12 young adult hamsters, each weighing 50 to 90 grams, with 0.25 ml of the diluted bacterin either subcutaneously or intramuscularly, in accordance with the label recommendations for use.

(2) *Controls.* Retain at least 10 but not more than 12 additional hamsters from the same group as unvaccinated controls.

(3) *Challenge.* From 14 to 18 days postvaccination, challenge each of 10 vaccinates and each of 10 controls intraperitoneally with a suspension of virulent *Leptospira grippotyphosa* organisms, using a dose of 10-10,000 hamster LD_{50} as determined by titration.

(4) *Post-challenge period.* Observe the vaccinates and controls for 14 days post-challenge and record all deaths. If eight or more controls die of leptospirosis, the test is valid and the results shall be evaluated according to the following table:

CUMULATIVE TOTALS

Stage	Number of vaccinates	Dead hamsters for acceptance	Dead hamsters for rejection
1	10	2 or less	5 or more.
2	20	5 or less	6 or more.

(5) If three or four vaccinates die in the first stage, the second stage shall be conducted in a manner identical to the first stage.

(6) If the second stage is used, each serial shall be evaluated according to the second part of the table. On the basis of cumulative results, each serial shall either pass or fail.

[40 FR 17003, Apr. 16, 1975, as amended at 40 FR 23989, June 4, 1975; 45 FR 40100, June 13, 1980]

§ 113.90 Leptospira Hardjo Bacterin.

Leptospira Hardjo Bacterin shall be produced from a culture of *Leptospira hardjo* which has been inactivated and is nontoxic. Each serial of biological product containing *Leptospira hardjo* fraction shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the test written into the filed Outline of Production.

[40 FR 17003, Apr. 16, 1975, as amended at 40 FR 20067, May 8, 1975]

§ 113.91 Clostridium Chauvoei Bacterin.

Clostridium Chauvoei Bacterin shall be produced from a culture of *Clostridium chauvoei* which has been inactivated and is nontoxic. Each serial of biological product containing *Clostridium chauvoei* fraction shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. Serials found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the two-stage test provided in this paragraph.

(1) Each of at least 8 but not more than 10 guinea pigs, each weighing 300 to 500 grams, shall be injected subcutaneously with a guinea pig dose. A second guinea pig dose shall be injected 21 to 23 days after the first dose. Each guinea pig dose shall be one-fifth of the dose recommended on the label for a calf.

(2) *Clostridium chauvoei* challenge material, available upon request from Veterinary Services, shall be used for challenge 14 to 15 days following the last injection of the product. Each of eight vaccinates and each of five additional nonvaccinated guinea pigs for controls shall be injected intramuscularly with approximately 100 LD_{50} of challenge material. This dose shall be determined by statistical analysis of results of titrations of the challenge material. The vaccinates and controls shall be observed for 3 days postchallenge and all deaths recorded.

(3) For a valid test, at least 80 percent of the controls shall die within the 3 day post-challenge observation period. If this requirement is met, the results of the potency test shall be evaluated according to the following table:

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total number of deaths for a satisfactory test	Cumulative total number of deaths for an unsatisfactory test
1	8	8	1 or less	3 or more.
2	8	16	4 or less	5 or more.

The second stage shall be required only when exactly two animals die in the first stage. The second stage shall be conducted in a manner identical to the first stage.

[39 FR 16862, May 10, 1974, as amended at 45 FR 40100, June 13, 1980]

§ 113.92 Clostridium Haemolyticum Bacterin.

Clostridium Haemolyticum Bacterin shall be produced from a culture of *Clostridium haemolyticum* which has been inactivated and is nontoxic. Each serial of biological product containing *Clostridium haemolyticum* fraction shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the two-stage test provided in this paragraph.

(1) Each of at least 8 but not more than 10 guinea pigs, each weighing 300 to 500 grams, shall be injected subcutaneously with a guinea pig dose. A second guinea pig dose shall be injected 21 to 23 days after the first dose. Each guinea pig dose shall be one-fifth of the dose recommended on the label for a calf.

(2) *Clostridium haemolyticum* challenge material, available upon request from Veterinary Services, shall be used for challenge 14 to 15 days following the last injection of the prod-

uct. Each of eight vaccinates and each of five additional nonvaccinated guinea pigs for controls shall be injected intramuscularly with approximately 100 LD$_{50}$ of challenge material. This dose shall be determined by statistical analysis of results of titrations of the challenge material. The vaccinates and controls shall be observed for 3 days postchallenge and all deaths recorded.

(3) For a valid test, at least 80 percent of the controls shall die within the 3 day post-challenge observation period. If this requirement is met, the results of the potency test shall be evaluated according to the following table:

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total number of deaths for a satisfactory test	Cumulative total number of deaths for an unsatisfactory test
1	8	8	1 or less	3 or more.
2	8	16	4 or less	5 or more.

The second stage shall be required only when exactly two animals die in the first stage. The second stage shall be conducted in a manner identical to the first stage.

[39 FR 16862, May 10, 1974, as amended at 40 FR 20067, May 8, 1975; 45 FR 40100, June 13, 1980]

§ 113.93 Clostridium Novyi Bacterin-Toxoid.

Clostridium Novyi Bacterin-Toxoid shall be produced from a culture of *Clostridium novyi* which has been inactivated and is nontoxic. Each serial of biological product containing *Clostridium novyi* fraction shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the following two-stage test provided in this paragraph.

(1) Each of at least 8 but not more than 10 guinea pigs, each weighing 300 to 500 grams, shall be injected subcutaneously with a guinea pig dose. A second guinea pig dose shall be injected 21 to 23 days after the first dose. Each guinea pig dose shall be one-fifth of the dose recommended on the label for a calf.

(2) *Clostridium novyi* challenge material, available upon request from Veterinary Services, shall be used for challenge 14 to 15 days following the last injection of the product. Each of eight vaccinates and each of five additional nonvaccinated guinea pigs for controls shall be injected intramuscularly with approximately 100 LD$_{50}$ of challenge material. This dose shall be determined by statistical analysis of results of titrations of the challenge material. The vaccinates and controls shall be observed for 3 days postchallenge and all deaths recorded.

(3) For a valid test, at least 80 percent of the controls shall die within the 3 day post-challenge observation period. If this requirement is met, the results of the potency test shall be evaluated according to the table:

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total number of deaths for a satisfactory test	Cumulative total number of deaths for an unsatisfactory test
1	8	8	1 or less	3 or more.
2	8	16	4 or less	5 or more.

The second stage shall be required only when exactly two animals die in the first stage. The second stage shall be conducted in a manner identical to the first stage.

[39 FR 16862, May 10, 1974, as amended at 45 FR 40101, June 13, 1980]

§ 113.94 Clostridium Sordellii Bacterin-Toxoid.

Clostridium Sordellii Bacterin-Toxoid shall be produced from a culture of *Clostridium sordellii* which has been inactivated and is nontoxic.

Each serial of biological product containing *Clostridium sordellii* fraction shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency by one of the following methods: A host animal test written into the filed Outline of Production, or the two-stage test provided in this paragraph.

(1) Each of at least 8 but not more than 10 guinea pigs, each weighing 300 to 500 grams, shall be injected subcutaneously with a guinea pig dose. A second guinea pig dose shall be injected 21 to 23 days after the first dose. Each guinea pig dose shall be one-fifth of the dose recommended on the label for a calf.

(2) *Clostridium sordellii* challenge material, available upon request from Veterinary Services, shall be used for challenge 14 to 15 days following the second injection of the product. Each of eight vaccinates and each of five additional nonvaccinated guinea pigs for controls shall be injected intramuscularly with approximately 100 LD_{50} of challenge material. This dose shall be determined by statistical analysis of results of titrations of the challenge material. The vaccinates and controls shall be observed for 3 days postchallenge and all deaths recorded.

(3) For a valid test, at least 80 percent of the controls shall die within the 3 day post-challenge observation period. If this requirement is met, the result of the potency test shall be evaluated according to the following table:

CUMULATIVE

Stage	Number of vaccinates	Deaths for a satisfactory test	Deaths for an unsatisfactory test
1	8	1 or less	3 or more.
2	16	4 or less	5 or more.

The second stage shall be required only when exactly two animals die in the first stage. The second stage shall be conducted in a manner identical to the first stage.

[39 FR 16862, May 10, 1974, as amended at 42 FR 61247, Dec. 2, 1977; 45 FR 40101, June 13, 1980]

§ 113.95 Clostridium Botulinum Type C Bacterin-Toxoid.

Clostridium Botulinum Type C Bacterin-Toxoid shall be produced from a culture of *Clostridium botulinum* Type C which has been inactivated and is nontoxic. Each serial of biological product containing *Clostridium botulinum* Type C fraction shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b).

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency, using susceptible mink as test animals. At least five vaccinates and three unvaccinated controls of the same source and approximately the same age shall be used.

(1) Each of the vaccinates shall be injected subcutaneously with the dose recommended on the label for mink. Twenty-one to twenty-eight days postinjection, the vaccinates and the controls shall be challenged intraperitoneally with botulinum Type C toxin which has been titrated in mice to pro-

vide for a 10^{+0} mouse MLD dose. The titration technique shall include inoculation of the mice intraperitoneally.

(2) The vaccinates and controls shall be observed for 7 days post-challenge and signs of botulism and deaths noted. For a valid test, the controls shall die of botulism. If the test is valid and 80 percent of the vaccinates do not remain free of botulism, the serial is unsatisfactory.

[39 FR 16862, May 10, 1974, as amended at 40 FR 759, Jan. 3, 1975]

§ 113.96 Clostridium Perfringens Type C Toxoid and Bacterin-Toxoid.

Clostridium Perfringens Type C Toxoid and Clostridium Perfringens Type C Bacterin-Toxoid shall be produced from a culture of *Clostridium perfringens* Type C which has been inactivated and is nontoxic. Each serial shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b).

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the Beta toxin-neutralization test provided in this paragraph.

(1) When used in this test, the following words and terms shall mean:

(i) *International antitoxin unit.* (I.U.) That quantity of Beta Antitoxin which reacts with L_0 and L^+ doses of Standard Toxin according to their definitions.

(ii) *L_0 dose.* The largest quantity of toxin which can be mixed with one unit of Standard Antitoxin and not cause sickness or death in injected mice.

(iii) *L_+ dose.* The smallest quantity of toxin which can be mixed with one unit of Standard Antitoxin and cause death in at least 80 percent of injected mice.

(iv) *Standard antitoxin.* The Beta Antitoxin preparation which has been standardized as to antitoxin unitage on the basis of the International *Clostridium perfringens* Beta Antitoxin Standard and which is either supplied by or acceptable to Veterinary Services. The antitoxin unit value shall be stated on the label.

(v) *Standard toxin.* The Beta toxin preparation which is supplied by or is acceptable to Veterinary Services.

(vi) *Diluent.* The solution used to make proper dilutions prescribed in this test. Such solutions shall be made by dissolving 1 gram of peptone and 0.25 grams of sodium chloride in each 100 ml of distilled water; adjusting the pH to 7.2; autoclaving at 250° F for 25 minutes; and storing at 4° C until used.

(2) Each of at least eight rabbits, each weighing 4–8 pounds, shall be injected subcutaneously with not more than half of the recommended cattle dose. The dose for a combination product having both Type C and Type D fractions shall be half of the recommended cattle dose: *Provided,* That if the product is recommended only for sheep, half of the recommended sheep dose shall be used. A second dose shall be given not less than 20 days nor more than 23 days after the first dose.

(3) Fourteen to seventeen days after the second dose, all surviving rabbits shall be bled and the serum tested for antitoxin content.

(i) When eight or more rabbits are bled, equal quantities of serum from each shall be combined and tested as a single pooled serum.

(ii) When only four to seven rabbits are bled, the serums shall be individually tested.

(iii) If less than four rabbits are available, the test is invalid and shall be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(4) The antitoxin content of the rabbit serums shall be determined as follows:

(i) Make a dilution of Standard Antitoxin to contain 10 International Units of antitoxin per ml.

(ii) Make one dilution of Standard Toxin to contain 10 L_0 doses per ml and make a second dilution of Standard Toxin to contain 10 L_+ doses per ml.

(iii) Combine 10 International Units of Standard Antitoxin with 10 L_o doses of diluted Standard Toxin and combine 10 International Units of Standard Antitoxin with 10 L_+ doses of diluted Standard Toxin.

(iv) Combine 1 ml of undiluted serum with 10 L_o doses of diluted Standard Toxin.

(v) Neutralize all toxin-antitoxin mixtures at room temperature for 1 hour and hold in ice water until injections of mice can be made.

(vi) Five Swiss white mice, each weighing 16–20 grams, shall be used for each toxin-antitoxin mixture. A dose of 0.2 ml shall be injected intravenously into each mouse. Conclude the test 24 hours post-injection and record all deaths.

(5) Test Interpretation shall be as follows:

(i) If any mice inoculated with the mixture of 10 International Units of Standard Antitoxin and 10 L_o doses of Standard Toxin die, the results of the test are inconclusive and shall be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(ii) If less than 80 percent of the mice inoculated with mixture of 10 International Units of Standard Antitoxin and 10 L_+ doses of Standard Toxin die, the results of the test are inconclusive and shall be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(iii) If any mice inoculated with the mixture of serum with 10 L_o doses of Standard Toxin die, the serum is considered to contain less than 10 International Units per ml.

(iv) If less than 4 of 4 or less than 80 percent of individual serums from at least five to seven rabbits or if the single pooled serum from eight or more rabbits contain(s) less than 10 International Units per ml, the serial is unsatisfactory.

[39 FR 16862, May 10, 1974, as amended at 40 FR 759, Jan. 3, 1975; 40 FR 41088, Sept. 5, 1975]

§ 113.97 Clostridium Perfringens Type D Toxoid and Bacterin-Toxoid.

Clostridium Perfringens Type D Toxoid and Clostridium Perfringens Type D Bacterin-Toxoid shall be produced from a culture of *Clostridium perfringens* Type D which has been inactivated and is nontoxic. Each serial shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b).

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the Epsilon toxin-neutralization test provided in this paragraph.

(1) When used in this test, the following words and terms shall mean:

(i) *International antitoxin unit.* (I.U.) That quantity of Epsilon Antitoxin which reacts with L_o and L_+ doses of Standard Toxin according to their definitions.

(ii) *L_o dose.* The largest quantity of toxin which can be mixed with one-tenth unit of Standard Antitoxin and not cause sickness or death in injected mice.

(iii) *L_+ dose.* The smallest quantity of toxin which can be mixed with one-tenth unit of Standard Antitoxin and cause death in at least 80 percent of injected mice.

(iv) *Standard antitoxin.* The Epsilon Antitoxin preparation which has been standardized as to antitoxin unitage on the basis of the International *Clostridium perfringens* Epsilon Antitoxin Standard and which is either supplied by or acceptable to Veterinary Services. The antitoxin unit value shall be stated on the label.

(v) *Standard toxin.* The Epsilon toxin preparation which is supplied by or is acceptable to Veterinary Services.

(vi) *Diluent.* The solution used to make proper dilutions prescribed in this test. Such solutions shall be made by dissolving 1 gram of peptone and 0.25 gram of sodium chloride in each 100 ml of distilled water; adjusting the pH to 7.2; autoclaving at 250° F for 25 minutes; and storing at 4° C until used.

(2) Each of at least eight rabbits, each weighing 4–8 pounds, shall be injected subcutaneously with not more than half of the recommended sheep dose. The dose for a combination product having both Type C and Type D fractions shall be half of the recommended cattle dose: *Provided,* That, if the product is recommended only for sheep, half of the recommended sheep dose shall be used. A second dose shall be given not less than 20 days nor more than 23 days after the first dose.

(3) Fourteen to seventeen days after the second dose, all surviving rabbits shall be bled, and the serum tested for antitoxin content.

(i) When eight or more rabbits are bled, equal quantities of serum from each shall be combined and tested as a single pooled serum.

(ii) When only four to seven rabbits are bled, the serums shall be individually tested.

(iii) If less than four rabbits are available, the test is invalid and shall be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(4) The antitoxin content of the rabbit serums shall be determined as follows:

(i) Make a dilution of Standard Antitoxin to contain 1 International Unit of antitoxin per ml.

(ii) Make one dilution of Standard Toxin to contain 10 L_0 doses per ml and make a second dilution of Standard Toxin to contain 10 L_+ doses per ml.

(iii) Combine 1 International Unit of Standard Antitoxin with 10 L_0 doses of diluted Standard Toxin and Combine 1 International Unit of Standard Antitoxin with 10 L_+ doses of diluted Standard Toxin.

(iv) Dilute 1 ml of serum with 1 ml of diluent (1:2) and combine 1 ml of this solution with 10 L_0 doses of diluted Standard Toxin.

(v) Neutralize all toxin-antitoxin mixtures at room temperature for 1 hour and hold in ice water until injections of mice can be made.

(vi) Five Swiss white mice, each weighing 16–20 grams, shall be used for each toxin-antitoxin mixture. A dose of 0.2 ml shall be injected intravenously into each mouse. Conclude the test 24 hours post-injection and record all deaths.

(5) Test Interpretation shall be as follows:

(i) If any mice inoculated with the mixture of 1 International Unit of Standard Antitoxin and 10 L_0 doses of Standard Toxin die, the results of the test are inconclusive and shall be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(ii) If less than 80 percent of the mice inoculated with mixture of 1 International Unit of Standard Antitoxin and 10 L_+ doses of Standard Toxin die, the results of the test are inconclusive and shall be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(iii) If any mice inoculated with the mixture of serum with 10 L_0 doses of Standard Toxin die, the serum is considered to contain less than 2 International Units per ml.

(iv) If less than four of four or less than 80 percent of individual serums from at least five to seven rabbits or if the single pooled serum from eight or more rabbits contain(s) less than 2 International Units per ml, the serial is unsatisfactory.

[39 FR 16865, May 10, 1974; 39 FR 20783, June 14, 1974. Redesignated at 39 FR 25463, July 11, 1974, and amended at 40 FR 759, Jan. 3, 1975; 40 FR 41088, Sept. 5, 1975]

§ 113.98 Autogenous biologics.

Autogenous biologics shall be prepared from a culture of micro-organisms which has been inactivated and is nontoxic. Each serial shall meet the requirements in this section and if found unsatisfactory by any prescribed test shall not be used.

(a) *Seed requirements.* The micro-organisms used as seed shall be isolated from sick or dead animals or birds and judged to be the causative agent of the current disease affecting such animals or birds.

(1) More than one isolate from the same specimen(s) may be used.

(2) Under normal circumstances, isolates from one herd or flock shall not be used to prepare an autogenous biologic for another herd or flock. However, the Deputy Administrator may authorize preparation of an autogenous biologic for use in adjacent herds or flocks which are considered to be at risk. The Deputy Administrator may authorize preparation of an autogenous biologic for use in other herds or flocks (not adjacent) which he considers to be at risk, with written concurrence from proper State authorities.

(3) Isolates used to prepare autogenous biologics shall not be maintained in the licensed establishment beyond the time required to prepare authorized amounts.

(b) Unless otherwise authorized by the Deputy Administrator, each serial of an autogenous biologic shall be subject to the following restrictions:

(1) Autogenous biologics shall be prepared for emergency use only. Organisms shall not be used for production more than 12 months from isolation.

(2) The expiration date shall not exceed 18 months from harvest.

(c) *Testing Requirements.* Final container samples of completed product from each serial and subserial shall be tested for purity as prescribed in § 113.26, and for safety as prescribed in § 113.33(b) or § 113.38 except that:

(1) Serials which are satisfactory after the third day observation of purity test cultures and safety test animals may be released for shipment to the customer and the tests continued throughout the required period; and

(2) Serials released on the basis of satisfactory results of third day observations shall be immediately recalled if evidence of contamination occurs in test cultures or if any of the safety test animals sicken or die during the observation period.

[39 FR 29915, Aug. 19, 1974, as amended at 48 FR 9506, Mar. 7, 1983]

§ 113.99 Tetanus Toxoid.

Tetanus Toxoid shall be produced from a culture of *Clostridium tetani* which has been inactivated and is nontoxic. The toxoid may be either absorbed, precipitated, or purified and concentrated. Each serial of biological product containing *tetanus toxoid* fraction shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial or subserial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b).

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency. A group of at least 10 guinea pigs, consisting of an equal number of males and females weighing 500 grams ± 10 percent shall each be injected subcutaneously with 0.4 of the dose recommended on the label for a horse.

(1) Six weeks after injection all surviving guinea pigs shall be bled and equal portions of serum, but not less than 0.5 ml from each, shall be pooled. Serum from not less than eight animals shall be used.

(2) The pooled serum shall contain at least 2.0 Antitoxin Units (A.U.) per ml as determined by titrating it in the manner prescribed for Tetanus Antitoxin in 9 CFR 113.251. A 1:10 and a 1:20 dilution of the serum shall be made. The dilutions shall be held at 20° to 25° C for 30 minutes prior to combining with a test does of Standard Toxin. The test dose of Standard Toxin shall be mixed in proper proportion with each dilution of pooled serum, incubated at 20° to 25° C for 1 hour and injected subcutaneously into two guinea pigs weighing between 340 and 380 grams.

(3) The test dose of the Standard Toxin shall be verified against 0.1 of a unit to Standard Antitoxin in two

guinea pigs weighing 340 to 380 grams which serve as control animals.

(4) Controls shall be observed until they are down and are unable to rise or stand under their own power. At this time they are euthanized and the time of death is recorded in hours. For a valid test the controls must reach this point with clinical signs of tetanus within 24 hours of each other and within an overall time of 60 to 120 hours. The clinical signs to be observed are increased muscle tonus, curvature of the spine, asymmetry of the body outline when the resting animal is viewed from above, generalized spastic paralysis, particularly of the extensor muscles, inability to rise from a smooth flat surface when the animal is placed on its side, or any combination of these signs. If the control guinea pigs do not respond in this manner, the test is invalid and shall be repeated. In a valid test, if the titer is at least 2.0 A.U. per ml, the serial is satisfactory. If the titer is at least 1.0, but less than 2.0 A.U. per ml, the retest provided for by paragraph (c)(5) of this section may be conducted. If the titer is less than 1.0. A.U. per ml, the serial is unsatisfactory and may not be retested.

(5) Serials with titers of at least 1.0 A.U. per ml, but less than 2.0 A.U. per ml in the initial test may be retested, but if the retest is not conducted the serial is unsatisfactory. The retest shall be conducted in the same manner as the initial test except that at least 20 guinea pigs, consisting of an equal number of males and females weighing 500 grams ±10 percent, shall be used as vaccinates and serum from not less than 18 animals shall be pooled for the toxin-antitoxin titration. In the retest, the pooled serum from vaccinated guinea pigs is diluted 1:25. If the retest titer is less than 2.5 A.U. per ml, the serial is unsatisfactory.

[39 FR 16862, May 10, 1974, as amended at 46 FR 23224, Apr. 24, 1981; 50 FR 24905, June 14, 1985]

§ 113.100 Staphylococcus Aureus Bacterin-Toxoid.

Staphylococcus Aureus Bacterin-Toxoid shall be prepared from toxoided broth cultures of selected toxogenic strains of *Staphylococcus aureus* which has been inactivated and is nontoxic. Each serial of biological product containing Staphylococcus Aureus Bacterin-Toxoid shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product shall be tested for safety as provided in § 113.33(b). Also, the rabbits used in the potency test provided in paragraph (c) of this section shall constitute an additional safety test. If unfavorable reactions attributable to the product occur in any of the rabbits during the observation period, the serial is unsatisfactory.

(c) *Potency test.* Rabbits, each weighing 2000-3000 grams, shall be used as test animals. Either a five rabbit individual serum test or an eight rabbit pooled serum test shall be conducted. At the start of the test, individual serums from the five rabbits or pooled serums from the eight rabbits shall contain less than 0.2 alpha antitoxin units per ml.

(1) Each rabbit shall be given a series of not more than three intramuscular injections at 7 day intervals (1.0 ml, 2.0 ml, 3.0 ml) and observed from 7-14 days following the third injection. At the end of the observation period, a blood sample shall be taken from each rabbit.

(2) The sample of serum from each rabbit, if the five rabbit individual test is conducted or a pooled sample of equal quantities of serum from the rabbits if the eight rabbit pooled serum test is conducted, shall be tested to determine the staphylococcus alpha antitoxin units per ml as provided in paragraphs (c) (3), (4), (5), (6), (7), and (8) of this section.

(3) Inactivate rabbit serum 56° C for 30 minutes.

(4) Make serial twofold dilutions of the serum samples and conduct the test, using 1 ml of the serial dilutions.

Appropriate controls should be included for accurate interpretations.

(5) Add 1 ml of the standardized toxin containing the established "Lh" dose. The "Lh" dose is the amount of toxin which when mixed with one unit of standard antitoxin produces a 50 percent hemolysis of rabbit red blood cells.

(6) Incubate toxin-antitoxin mixture at room temperature for 30 minutes and add 1 ml of a 1.5 percent suspension of washed freshly drawn rabbit red blood cells suspended in normal saline to each tube. Mix and incubate the combined product in a 37° C water bath for 1 hour. Refrigerate at 5° C overnight.

(7) Read the hemolysis produced and establish the 50 percent end point. The 50 percent end point of hemolysis should be established by determining the size of the button produced by the unlysed red blood cells.

(8) Determine the units of antitoxin per 1 ml of serum.

(9) If the individual samples from four of the five rabbits in the individual serum test or the pooled samples from the eight rabbits in the pooled serum test do not contain three alpha antitoxin units per ml, the serial is unsatisfactory.

[39 FR 16862, May 10, 1974]

§ 113.101 Pasteurella Multocida Bacterin, Avian Isolate, Type 4.

Pasteurella Multocida Bacterin, Avian Isolate, Type 4 shall be prepared from cultures of *Pasteurella multocida*, avian isolate, Type 4 (Little and Lyons classification), which have been inactivated, and are nontoxic. Each serial of biological product containing Pasteurella Multocida Bacterin, Avian Isolate, Type 4, shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency, as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product shall be tested for viable bacteria and fungi as provided in 9 CFR 113.26.

(b) *Safety test.* Observation of the vaccinated turkeys during the prechallenge period of the potency test provided in paragraph (c) of this section shall constitute the safety test. If unfavorable reactions that are attributable to the product occur, the serial is unsatisfactory. If unfavorable reactions that are not attributable to the product occur in one turkey, test results shall be determined by observing the remaining 20 turkeys. The test is inconclusive and may be repeated if unfavorable reactions that are not attributable to the product occur in two or more turkeys, but the serial is unsatisfactory if the test is not repeated.

(c) *Potency test.* Bulk or final container samples of completed product shall be tested for potency of the Type 4 strain, using the two-stage test provided in this paragraph. Turkeys at least 6 weeks old obtained from the same source and hatch shall be properly identified and used as provided in this paragraph.

(1) *Vaccinates.* Each of not more than 21 turkeys shall be vaccinated with the dose and by the route recommended on the label. A second dose shall be given after 3 weeks and the turkeys observed for an additional 2-week prechallenge period.

(2) *Positive controls.* Each of not more than 21 turkeys shall be vaccinated with two doses of a reference bacterin available from Veterinary Services upon request.

(3) *Unvaccinated controls.* Each of not more than 21 turkeys shall be held as controls.

(4) *Challenge.* Not less than 14 days after the second dose, each of 20 vaccinates, each of 20 positive controls, and each of 20 unvaccinated controls shall be challenged intramuscularly with virulent *Pasteurella multocida* strain P-1662, Type 4 (Little and Lyons classification), and observed daily for a 14-day postchallenge period. Only dead birds shall be considered in evaluating the product.

(5) *Validity requirements.* Twelve or more positive controls must survive and 16 or more unvaccinated controls must die for the test to be valid. If these requirements are met, the potency test results are evaluated according to stage one of the following table. The test is inconclusive and may be repeated if the validity requirements are

not met, but the serial is unsatisfactory if the test is not repeated.

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total number of dead vaccinates for—	
			Satisfactory serial	Unsatisfactory serial
1	20	20	6 or less	9 or more.
2	20	40	15 or less	16 or more.

(6) The serial shall pass or fail based on the stage one results of the potency test. However, the second stage may be conducted if seven or eight vaccinates die in stage one, but the serial is unsatisfactory if the second stage is not conducted.

(7) The second stage shall be conducted in a manner identical to the first stage. The serial shall be evaluated according to stage two of the table. On the basis of accumulated results from the data of both stage tests, a serial shall either pass or fail the second stage.

[47 FR 5795, Feb. 4, 1982; 47 FR 6817, Feb. 17, 1982]

§ 113.102 Pasteurella Multocida Bacterin, Avian Isolate, Type 1.

Pasteurella Multocida Bacterin, Avian Isolate, Type 1, shall be prepared from cultures of *Pasteurella multocida*, avian isolate, Type 1 (Little and Lyons classification), which have been inactivated and are nontoxic. Each serial of biological product containing Pasteurella Multocida Bacterin, Avian Isolate, Type 1, shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Observation of the vaccinated chickens during the prechallenged period of the potency test provided in paragraph (c) of this section shall constitute the safety test. If unfavorable reactions that are attributable to the product occur, the serial is unsatisfactory. If unfavorable reactions that are not attributable to the product occur in one chicken, test results shall be determined by observing the remaining 20 chickens. The test is inconclusive and may be repeated if unfavorable reactions that are not attributable to the product occur in two or more chickens, but the serial is unsatisfactory if the test is not repeated.

(c) *Potency test.* Bulk or final container samples of completed product shall be tested for potency of the Type 1 strain, using the two-stage test provided in this paragraph. Chickens, at least 12 weeks of age, obtained from the same source and hatch, shall be properly identified and used as provided in this paragraph.

(1) *Vaccinates.* Each of not more than 21 chickens shall be injected with the dose and by the route recommended on the label. A second dose shall be injected after 3 weeks and the chickens observed for an additional 2 week prechallenge period.

(2) *Positive controls.* Each of not more than 21 chickens shall be injected with two doses of a reference bacterin available from Veterinary Services upon request.

(3) *Unvaccinated controls.* Each of not more than 21 chickens shall be held as controls.

(4) *Challenge.* Not less than 14 days after the second injection, each of 20 vaccinates, each of 20 positive controls, and each of 20 unvaccinated controls shall be challenged intramuscularly with a minimum of 250 colony-forming units of virulent *Pasteurella multocida.* Strain X-73, Type 1 (Little and Lyons Classification) and observed daily for a 14 day post-challenge period. Only dead birds shall be considered in evaluating the product.

(5) *Validity requirements.* Twelve or more positive controls must survive and 16 or more unvaccinated controls must die for the test to be valid. If these requirements are met, the potency test results are evaluated according to stage one of the following table. The test is inconclusive and may be repeated if the validity requirements are not met, but the serial is unsatisfactory if the test is not repeated.

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total number of dead vaccinates for—	
			Satisfactory serial	Unsatisfactory serial
1	20	20	6 or less	9 or more.
2	20	40	15 or less	16 or more.

(6) The serial shall pass or fail based on the stage one results of the potency test. However, the second stage may be conducted if seven or eight vaccinates die in stage one, but the serial is unsatisfactory if the second stage is not conducted.

(7) The second stage shall be conducted in a manner identical to the first stage. The serial shall be evaluated according to stage two of the table. On the basis of accumulated results from the data of both stage tests, a serial shall either pass or fail the second stage.

[39 FR 16866, May 10, 1974; 39 FR 20368, June 10, 1974, as amended at 40 FR 759, Jan. 3, 1975; 40 FR 23989, June 4, 1975; 47 FR 5195, Feb. 4, 1982]

§ 113.103 Pasteurella Multocida Bacterin, Avian Isolate, Type 3.

Pasteurella Multocida Bacterin, Avian Isolate, Type 3, shall be prepared from culture of *Pasteurella multocida*, avian isolate, Type 3 (Little and Lyons classification), which have been inactivated and are nontoxic. Each serial of biological product containing Pasteurella Multocida Bacterin, Avian Isolate, Type 3, shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency, as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Observation of the vaccinated turkeys during the prechallenge period of the potency test provided in paragraph (c) of this section shall constitute the safety test. If unfavorable reactions that are attributable to the product occur, the serial is unsatisfactory. If unfavorable reactions that are not attributable to the product occur in one turkey, test results shall be determined by observing the remaining 20 turkeys. The test is inconclusive and may be repeated if unfavorable reactions that are not attributable to the product occur in two or more turkeys, but the serial is unsatisfactory if the test is not repeated.

(c) *Potency test.* Bulk or final container samples of completed product shall be tested for potency of the Type 3 strain, using the two-stage test provided in this paragraph. Turkeys, at least 6 weeks of age, obtained from the same source and hatch, shall be properly identified and used as provided in this paragraph.

(1) *Vaccinates.* Each of not more than 21 turkeys shall be injected with the dose and by the route recommended on the label. A second dose shall be injected after 3 weeks and the turkeys observed for an additional 2 week prechallenge period.

(2) *Positive controls.* Each of not more than 21 turkeys shall be injected with two doses of a reference bacterin available from Veterinary Services upon request.

(3) *Unvaccinated controls.* Each of not more than 21 turkeys shall be held as controls.

(4) *Challenge.* Not less than 14 days after the second injection, each of 20 vaccinates, each of 20 positive controls, and each of 20 unvaccinated controls shall be challenged intramuscularly with a minimum of 150 colony-forming units of virulent *Pasteurella multocida* Strain P-1059, Type 3 (Little and Lyons Classification) and observed daily for a 14 day post-challenge period. Only dead birds shall be considered in evaluating the product.

(5) *Validity requirements.* Twelve or more positive controls must survive and 16 or more unvaccinated controls must die for the test to be valid. If these requirements are met, the potency test results are evaluated according to stage one of the following table. The test is inconclusive and may be repeated if the validity requirements are not met, but the serial is unsatisfactory if the test is not repeated.

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total number of dead vaccinates for—	
			Satisfactory serial	Unsatisfactory serial
1	20	20	6 or less	9 or more.
2	20	40	15 or less	16 or more.

(6) The serial shall pass or fail based on the stage one results of the potency test. However, the second stage may be conducted if seven or eight vaccinates die in stage one, but the serial is unsatisfactory if the second stage is not conducted.

(7) The second stage shall be conducted in a manner identical to the first stage. The serial shall be evaluated according to stage two of the table. On the basis of accumulated results from the data of both stage tests, a serial shall either pass or fail the second stage.

[39 FR 16862, May 10, 1974, as amended at 40 FR 759, Jan. 3, 1975; 47 FR 5196, Feb. 4, 1982]

§ 113.104 Erysipelothrix Rhusiopathiae Bacterin.

Erysipelothrix Rhusiopathiae Bacterin shall be produced from a culture of *Erysipelothrix rhusiopathiae* which has been inactivated and is nontoxic. Each serial of biological product containing *Erysipelothrix rhusiopathiae* shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the mouse protection test provided in this paragraph. A mouse dose shall be $1/10$ of the least dose recommended on the label for swine. Such swine dose shall not be less than 1 ml.

(1) The ability of the bacterin being tested (Unknown) to protect mice shall be compared with a Standard Reference Bacterin (Standard) which is either supplied by or acceptable to Veterinary Services.

(2) At least three threefold dilutions shall be made with the Standard and the same threefold dilutions shall be made for each Unknown. Dilutions shall be made with physiological saline solution.

(3) For each dilution of the Standard and each dilution of an Unknown, a group of at least 20 mice, each weighing 16 to 22 grams, shall be used. Each mouse in each group shall be injected subcutaneously with one mouse dose of the appropriate dilution.

(4) Each of 20 injected mice from each group shall be challenged subcutaneously 14 to 21 days after being injected. A dose containing at least 100 mouse LD_{50} of a suitable culture of *Erysipelothrix rhusiopathiae* shall be used. All survivors in each group of mice shall be recorded 10 days postchallenge.

(5) Test for valid assay: At least two dilutions of the Standard shall protect more than 0 percent and two dilutions shall protect less than 100 percent of the mice injected. The lowest dilution of the Standard shall protect more than 50 percent of the mice. The highest dilution of the Standard shall protect less than 50 percent of the mice.

(6) The relative potency (RP) of the Unknown is determined by comparing the 50 percent endpoint dilution (highest bacterin dilution protecting 50 percent of the mice) of the Unknown with that of the standard by the following formula:

$$\text{RP}=\frac{\text{Reciprocal of 50 percent endpoint dilution of Unknown}}{\text{Reciprocal of 50 percent endpoint dilution of Standard}}$$

(7) If the RP of the Unknown is less than 0.6, the serial being tested is unsatisfactory.

(8) If the 50 percent endpoint of an Unknown in a valid test cannot be calculated because the lowest dilution does not exceed 50 percent protection, that serial may be retested in a manner identical to the initial test: *Provided*, That, if the Unknown is not retested or if the protection provided by the lowest dilution of the Standard exceeds the protection provided by the lowest dilution of the Unknown by six mice or more; or, if the total number of mice protected by the Standard exceeds the total number of mice protected by the Unknown by eight mice or more, the serial is unsatisfactory.

(9) If the 50 percent endpoint of an Unknown in a valid test cannot be calculated because the highest dilution exceeds 50 percent protection, the Unknown is satisfactory without additional testing.

(10) If the RP is less than 0.6, the serial may be retested by conducting two independent replicate tests in a manner identical to the initial test. The average of the RP values obtained in the retests shall be determined. If the average RP is less than 0.6, the serial is unsatisfactory without further testing. If the average RP obtained in the retests is equal to or greater than 0.6, the following shall apply:

(i) If the RP obtained in the original test is one-third or less than the average RP obtained in the retests, the initial RP may be considered a result of test system error and the serial is satisfactory for potency.

(ii) If the RP value obtained in the original test is more than one-third the average RP obtained in the retests, a new average shall be determined using the RP values obtained in all tests. If the new average is less than 0.6, the serial is unsatisfactory.

(d) When the mouse protection test is conducted, the ability of the bacterin to be tested (Unknown) to protect mice shall be compared with a standard bacterin (Standard) which is either supplied by or is acceptable to Veterinary Services.

(1) A mouse dose in this test shall be 1/10 of the least dose recommended on the label for swine. Such swine dose shall not be less than 1 ml. At least three threefold dilutions shall be made with the Unknown. Dilutions shall be made with physiological saline solution.

(2) For each dilution of the Standard and each dilution of the Unknown, a group of 16 mice, each weighing 16 to 20 grams, shall be used. Each mouse in a group shall be injected subcutaneously with one mouse dose of the appropriate dilution.

(3) Each injected mouse shall be challenged subcutaneously 14 to 21 days after being injected with the diluted bacterin. A 0.2 ml dose containing at least 100 mouse LD_{50} of a suitable culture of ***Erysipelothrix rhusiopathiae*** shall be used. All survivors in each group of mice shall be recorded 10 days post-challenge.

(4) Test for valid assay: At least two dilutions of the Standard shall protect more than 0 percent and two dilutions shall protect less than 100 percent of the mice injected. The lowest dilution of the Standard shall protect more than 50 percent of the mice. The highest dilution of the Standard shall protect less than 50 percent of the mice.

(5) Determine the total number of surviving mice in three consecutive dilutions of the Standard that satisfy validity require requirements of paragraph (d)(4) of this section. Determine the total number of surviving mice in the same three dilutions of the Unknown. If the total number of survivors for the Standard exceeds the total number of survivors for the Un-

known by a number greater than six, the Unknown is unsatisfactory.

(e) When the swine protection test is conducted, susceptible pigs shall be used as test animals. Each of four pigs (vaccinates) shall be injected with one pig dose as recommended on the label. Four additional pigs shall be held as unvaccinated controls. Fourteen to twenty-one days postvaccination, the vaccinates and the controls shall be challenged with a virulent *Erysipelothrix rhusiopathiae* culture by the intramuscular route and observed for 7 days.

(1) A satisfactory challenge shall be evidenced in the controls by a bacteremia, a high body temperature, and clinical signs of sickness, including but not limited to acute illness with hyperemia of the abdomen and ears possibly terminating in sudden death; moribund and anorexia, with or without metastatic skin lesions; slowness with variable anorexia, stiffness, and/or joint involvement; and any combination of these symptoms and lesions.

(2) If at least 75 percent of the controls do not show characteristic symptoms of swine erysipelas during the observation period, including but not limited to a body temperature of 105.6° F. or higher on at least 2 days or 107° F. or higher for at least 16 hours, the test shall be considered inconclusive: *Provided*, That control pigs which meet the criteria requirements for susceptibility except for high body temperature shall be considered susceptible if sacrificed and organisms identified as *Erysipelothrix rhusiopathiae* can be isolated from the blood, spleen, or other organs.

(3) To demonstrate immunity after challenge, the vaccinates shall remain free of lesions or symptoms of erysipelas and the body temperature shall not exceed 104.6° F. for longer than 1 day. If at least 75 percent of the vaccinates do not demonstrate immunity to erysipelas throughout the observation period, the serial or subserial is unsatisfactory.

[39 FR 16862, May 10, 1974, as amended at 40 FR 759, Jan. 3, 1975; 40 FR 20067, May 8, 1975; 40 FR 51414, Nov. 5, 1975; 44 FR 71408, Dec. 11, 1979; 50 FR 23795, June 6, 1985]

§ 113.105 Salmonella Typhimurium Bacterin.

Salmonella Typhimurium Bacterin shall be prepared from a culture of *Salmonella typhimurium* which has been inactivated and is nontoxic. Each serial of biological product containing *Salmonella typhimurium* fraction shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33b.

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the mouse test provided in this paragraph. A mouse dose shall be 1/20 of the least dose recommended on the label for other animals which shall not be less than 2 ml.

(1) The ability of the bacterin being tested (Unknown) to protect mice shall be compared with a Standard Reference Bacterin (Standard) which is either supplied by or acceptable to Veterinary Services.

(2) At least three tenfold dilutions shall be made with the Standard and the same tenfold dilutions shall be made for each Unknown. The dilutions shall be made in Phosphate Buffered Saline.

(3) For each dilution of the Standard and each dilution of an Unknown, a group of at least 20 mice, each weighing 16-22 grams, shall be used. Each mouse in a group shall be injected intraperitoneally with one mouse dose of the appropriate dilution. Each mouse shall be revaccinated on day 14, using the same schedule.

(4) Each of 20 vaccinated mice per group shall be challenged intraperitoneally 7-10 days afer the second vaccination with a 0.25 ml dose containing 100-10,000 mouse LD_{50} as determined by titration, of a suitable culture of *Salmonella typhimurium.* All survivors

in each group of mice shall be recorded 14 days postchallenge.

(5) Test for valid assay: At least two dilutions of the Standard shall protect more than 0 percent and two dilutions shall protect less than 100 percent of the mice injected. The lowest dilution of the Standard shall protect more than 50 percent of the mice. The highest dilution of the Standard shall protect less than 50 percent of the mice.

(6) The relative potency (RP) of the Unknown is determined by comparing the 50 percent endpoint dilution (highest bacterin dilution protecting 50 percent of the mice) of the Unknown with that of the Standard by the following formula:

$$RP = \frac{\text{reciprocal of 50 percent endpoint dilution of Unknown}}{\text{reciprocal of 50 percent endpoint dilution of Standard}}$$

(7) If the RP of the Unknown is less than 0.30, the serial being tested is unsatisfactory.

(8) If the 50 percent endpoint of an Unknown cannot be calculated because the lowest dilution does not exceed 50 percent protection, that serial may be retested in a manner identical to the initial test; *Provided*, That, if the Unknown is not retested or if the protection provided by the lowest dilution of the Unknown by six mice or more; or, if the total number of mice protected by the Standard exceeds the total number of mice protected by the Unknown by eight mice or more, the serial being tested is unsatisfactory.

(9) If the 50 percent endpoint of an Unknown in a valid test cannot be calculated because the highest dilution exceeds 50 percent protection, the Unknown is satisfactory without additional testing.

(10) If the RP is less than the minimum required in paragraph (c)(7) of this section, the serial may be retested by conducting two independent replicate tests in a manner identical to the initial test. The average of the RP values obtained in the retests shall be determined. If the average RP is less than the required minimum, the serial is unsatisfactory. If the average RP obtained in the retests is equal to or greater than the required minimum, the following shall apply:

(i) If the RP obtained in the original test is one-third or less than the average RP obtained in the retests, the initial RP may be considered a result of test system error and the serial is satisfactory.

(ii) If the RP value obtained in the original test is more than one-third the average RP obtained in the retests, a new average shall be determined using the RP values obtained in all tests. If the new average is less than the minimum required in paragraph (c)(7) of this section, the serial is unsatisfactory.

[40 FR 17003, Apr. 16, 1975, as amended at 42 FR 59487, Nov. 18, 1977; 48 FR 31008, July 6, 1983]

§ 113.106 Pasteurella Multocida Bacterin.

Pasteurella Multocida Bacterin shall be prepared from a culture of *Pasteurella multocida* strains other than avian which have been inactivated and are nontoxic. Each serial of biological product containing *Pasteurella multocida* fraction shall meet the applicable requirements in § 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b). The subcutaneous route is to be used.

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the mouse test provided in this paragraph. A mouse dose shall be 1/20 of the least dose recommended on the label for other animals which shall not be less than 2 ml.

(1) The ability of the bacterin being tested (Unknown) to protect mice shall be compared with a Standard Reference Bacterin (Standard) which is either supplied by or acceptable to Veterinary Services.

(2) At least three fivefold dilutions shall be made with the Standard and the same fivefold dilutions shall be made for each Unknown. The dilutions will be made in Phosphate Buffered Saline.

(3) For each dilution of the Standard and each dilution of each Unknown, a group of at least 20 mice, each weighing 16-22 grams, shall be used. Each mouse in a group shall be injected intraperitoneally with one mouse dose of the appropriate dilution. Each mouse shall be revaccinated on day 14, using the same schedule.

(4) Each of 20 injected mice per group shall be challenged intraperitoneally 10-12 days after the second vaccination with a 0.2 ml dose containing 100-10,000 mouse LD_{50}., as determined by titration, of a suitable culture of *Pasteurella multocida*. All survivors in each group of mice shall be recorded 10 days postchallenge.

(5) Test for valid assay: At least two dilutions of the Standard shall protect more than 0 percent and two dilutions shall protect less than 100 percent of the mice injected. The lowest dilution of the Standard shall protct more than 50 percent of the mice. The highest dilution of the Standard shall protect less than 50 percent of the mice.

(6) The relative potency (RP) of the Unknown is determined by comparing the 50 percent endpoint dilution (highest bacterin dilution protecting 50 percent of the mice) of the Unknown with that of the Standard, by the following formula:

$$RP = \frac{\text{reciprocal of 50 percent endpoint dilution of Unknown}}{\text{reciprocal of 50 percent endpoint dilution of Standard}}$$

(7) If the RP of the Unknown is less than 0.50, the serial being tested is unsatisfactory.

(8) If the 50 percent endpoint of an Unknown cannot be calculated because the lowest dilution does not exceed 50 percent protection, that serial may be retested in a manner identical to the initial test; *Provided*, That, if the Unknown is not retested or if the protection provided by the lowest dilution of the Standard exceeds the protection provided by the lowest dilution of the Unknown by six mice or more; or, if the total number of mice protected by the Standard exceeds the total number of mice protected by the Unknown by eight mice or more, the serial being tested is unsatisfactory.

(9) If the 50 percent endpoint of an Unknown in a valid test cannot be calculated because the highest dilution exceeds 50 percent protection, the Unknown is satisfactory without additional testing.

(10) If the RP is less than the minimum required in paragraph (c)(7) of this section, the serial may be retested by conducting two independent replicate tests in a manner identical to the initial test. The average of the RP values obtained in the retests shall be determined. If the average RP is less than the required minimum, the serial is unsatisfactory. If the average RP obtained in the retests is equal to or greater than the required minimum, the following shall apply:

(i) If the RP obtained in the original test is one-third or less than the average RP obtained in the retests, the initial RP may be considered a result of test system error and the serial is satisfactory.

(ii) If the RP value obtained in the original test is more than one-third the average RP obtained in the retests, a new average shall be determined using the RP values obtained in all tests. If the new average is less than the minimum required in paragraph (c)(7) of this section, the serial is unsatisfactory.

[40 FR 17004, Apr. 16, 1975, as amended at 42 FR 59487, Nov. 18, 1977; 48 FR 31008, July 6, 1983]

§ 113.107 Salmonella Choleraesuis Bacterin.

Salmonella Choleraesuis Bacterin shall be prepared from a culture of *Salmonella choleraesuis* which has been inactivated and is nontoxic. Each serial of biological product containing *Salmonella choleraesuis* fraction shall meet the applicable requirements in 9 CFR 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product shall be tested for viable bacteria and fungi as provided in 9 CFR 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in 9 CFR 113.33(b).

The subcutaneous route shall be used when the product is in combination with Pasteurella Multocida Bacterin.

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the mouse test provided in this paragraph. A mouse dose shall be $\frac{1}{20}$ of the least dose recommended on the label for other animals which shall not be less than 2 ml.

(1) The ability of the bacterin being tested (Unknown) to protect mice shall be compared with a Standard Reference Bacterin (Standard) which is either supplied by or acceptable to Veterinary Services.

(2) At least three fivefold dilutions shall be made with the Standard and the same fivefold dilution shall be made for each Unknown. The dilutions shall be made in Phosphate-Buffered Saline.

(3) For each dilution of the Standard and each dilution of an Unknown, a group of at least 20 mice, each weighing 16 to 22 grams, shall be used. Each mouse in a group shall be injected intraperitoneally with one mouse dose of the appropriate dilution. Each mouse shall be revaccinated on day 14, using the same schedule.

(4) Each of 20 vaccinated mice per group shall be challenged intraperitoneally 7 to 10 days after the second vaccination with a 0.25 ml dose containing 10–1,000 mouse LD_{50} as determined by titration of a suitable culture of *Salmonella choleraesuis*. All survivors in each group of mice shall be recorded 14 days postchallenge.

(5) Test for valid assay: At least two dilutions of the Standard shall protect more than 0 percent and two dilutions shall protect less than 100 percent of the mice injected. The lowest dilution of the Standard shall protect more than 50 percent of the mice. The highest dilution of the Standard shall protect less than 50 percent of the mice.

(6) The relative potency (RP) of the Unknown is determined by comparing the 50 percent endpoint dilution (highest bacterin dilution protecting 50 percent of the mice) of the Unknown with that of the Standard by the following formula:

RP=Reciprocal of 50 percent endpoint dilution of Unknown/Reciprocal of 50 percent endpoint dilution of Standard.

(7) If the RP of the Unknown is less than 0.50, the serial being tested is unsatisfactory.

(8) If the 50 percent endpoint of an Unknown cannot be calculated because the lowest dilution does not exceed 50 percent protection, that serial may be retested in a manner identical to the initial test; *Provided,* That, if the Unknown is not retested or if the protection provided by the lowest dilution of the Standard exceeds the protection provided by the lowest dilution of the Unknown by six mice or more; or, if the total number of mice protected by the Standard exceeds the total number of mice protected by the Unknown by eight mice or more, the serial being tested is unsatisfactory.

(9) If the 50 percent endpoint of an Unknown in a valid test cannot be calculated because the highest dilution exceeds 50 percent protection, the Unknown is satisfactory without additional testing.

(10) If the RP is less than the minimum required in paragraph (c)(7) of this section, the serial may be retested by conducting two independent replicate tests in a manner identical to the initial test. The average of the RP values obtained in the retests shall be determined. If the average RP is less than the required minimum, the serial is unsatisfactory. If the average RP obtained in the retests is equal to or greater than the required minimum, the following shall apply:

(i) If the RP obtained in the original test is one-third or less than the average RP obtained in the retests, the initial RP may be considered a result of test system error and the serial is satisfactory.

(ii) If the RP value obtained in the original test is more than one-third the average RP obtained in the retests, a new average shall be determined using the RP values obtained in all tests. If the new average is less than the minimum required in paragraph (c)(7) of this section, the serial is unsatisfactory.

[43 FR 25077, June 9, 1978, as amended at 48 FR 31008, July 6, 1983]

§ 113.108 Salmonella Dublin Bacterin.

Salmonella Dublin Bacterin shall be prepared from a culture of *Salmonella dublin* which has been inactivated and is nontoxic. Each serial of biological product containing *Salmonella dublin* fraction shall meet the applicable requirements in 9 CFR 113.85 and shall be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product shall be tested for viable bacteria and fungi as provided in 9 CFR 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in 9 CFR 113.33(b).

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the mouse test provided in this paragraph. A mouse dose shall be 1/20 of the least dose recommended on the label for other animals which shall not be less than 2 ml.

(1) The ability of the bacterin being tested (Unknown) to protect mice shall be compared with a Standard Reference Bacterin (Standard) which is either supplied by or acceptable to Veterinary Services.

(2) At least three tenfold dilutions shall be made with the Standard and the same tenfold dilutions shall be made for each Unknown. The dilutions shall be made in Phosphate-Buffered Saline.

(3) For each dilution of the Standard and each dilution of an Unknown, a group of at least 20 mice, each weighing 16 to 22 grams, shall be used. Each mouse in a group shall be injected intraperitoneally with one mouse dose of the appropriate dilution. Each mouse shall be revaccinated on day 14, using the same schedule.

(4) Each of 20 vaccinated mice per group shall be challenged intraperitoneally 7 to 10 days after the second vaccination with a 0.25 ml dose containing 1,000-100,000 mouse LD$_{50}$ as determined by titration of a suitable culture of *Salmonella dublin*. All survivors in each group of mice shall be recorded 14 days postchallenge.

(5) Test for valid assay: At least two dilutions of the Standard shall protect more than 0 percent and two dilutions shall protect less than 100 percent of the mice injected. The lowest dilution of the Standard shall protect more than 50 percent of the mice. The highest dilution of the Standard shall protect less than 50 percent of the mice.

(6) The relative potency (RP) of the Unknown is determined by comparing the 50 percent endpoint dilution (highest bacterin dilution protecting 50 percent of the mice) of the Unknown with that of the Standard by the following formula:

RP = Reciprocal of 50 percent endpoint dilution of Unknown/Reciprocal of 50 percent endpoint dilution of Standard.

(7) If the RP of the Unknown is less than 0.30, the serial being tested is unsatisfactory.

(8) If the 50 percent endpoint of an Unknown cannot be calculated because the lowest dilution does not exceed 50 percent protection, that serial may be retested in a manner identical to the initial test; *Provided*, That, if the Unknown is not retested or if the protection provided by the lowest dilution of the Standard exceeds the protection provided by the lowest dilution of the Unknown by six mice or more; or, if the total number of mice protected by the Standard exceeds the total number of mice protected by the Unknown by eight mice or more, the serial being tested is unsatisfactory.

(9) If the 50 percent endpoint of an Unknown in a valid test cannot be calculated because the highest dilution exceeds 50 percent protection, the Unknown is satisfactory without additional testing.

(10) If the RP is less than the minimum required in paragraph (c)(7) of this section, the serial may be retested by conducting two independent repli-

cate tests in a manner identical to the initial test. The average of the RP values obtained in the retests shall be determined. If the average RP is less than the required minimum, the serial is unsatisfactory. If the average RP obtained in the retests is equal to or greater than the required minimum, the following shall apply:

(i) If the RP obtained in the original test is one-third or less than the average RP obtained in the retests, the initial RP may be considered a result of test system error and the serial is satisfactory.

(ii) If the RP value obtained in the original test is more than one-third the average RP obtained in the retests, a new average shall be determined using the RP values obtained in all tests. If the new average is less than the minimum required in paragraph (c)(7) of this section, the serial is unsatisfactory.

[43 FR 25077, June 9, 1978, as amended at 48 FR 31009, July 6, 1983]

KILLED VIRUS VACCINES

§ 113.120 General requirements for killed virus vaccines.

When prescribed in an applicable Standard Requirement or in the filed Outline of Production, a killed virus vaccine shall meet the applicable requirements in this section.

(a) *Killing Agent.* The vaccine virus shall be killed (inactivated) by an appropriate agent. The procedure involved may be referred to as inactivation. Suitable tests to assure complete inactivation shall be written into the filed Outline of Production.

(b) *Cell Culture Requirements.* If cell cultures are used in the preparation of the vaccine, primary cells shall meet the requirements in § 113.51 and cell lines shall meet the requirements in § 113.52.

(c) *Purity Tests*—(1) *Bacteria and fungi.* Final container samples of completed product from each serial shall be tested as prescribed in § 113.26.

(2) *Avian Origin Vaccine.* Bulk pooled material or final container samples from each serial shall also be tested for:

(i) *Salmonella* contamination as prescribed in § 113.30; and

(ii) *Lymphoid leukosis virus* contamination as prescribed in § 113.31; and

(iii) *Hemagglutinating viruses* as prescribed in § 113.34.

(3) *Mycoplasma.* If the licensee cannot demonstrate that the agent used to kill the vaccine virus would also kill mycoplasma, each serial of the vaccine shall be tested for mycoplasma as prescribed in § 113.28, prior to adding the killing agent. Material found to contain mycoplasma is unsatisfactory for use.

(4) *Extraneous viruses.* Each lot of Master Seed Virus used to prepare killed virus vaccine recommended for animals other than poultry shall meet the requirements for extraneous viruses as prescribed in § 113.55.

(d) *Safety Tests.* Final container samples of completed product from each serial shall be tested for safety in guinea pigs as prescribed in § 113.38 and for safety in mice as prescribed in § 113.33: *Provided,* That, vaccines recommended for use only in poultry are exempt from this requirement.

(e) *Viricidal Activity Test.* Only serials tested for viricidal activity in accordance with the test provided in § 113.35 and found satisfactory by such test shall be packaged as diluent for desiccated fractions in combination packages.

(f) *Formaldehyde content.* If formaldehyde is used as the killing agent, the residual free formaldehyde content shall not exceed the equivalent of 0.2 percent formaldehyde solution (740 parts per million formaldehyde).

[39 FR 27428, July 29, 1974, as amended at 40 FR 23989, June 4, 1975; 43 FR 49528, Oct. 24, 1978]

§ 113.121 Canine Distemper Vaccine, Killed Virus.

Canine Distemper Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids or tissues obtained from animals that have developed canine distemper following inoculation with virulent canine distemper virus. Each serial shall meet the applicable general requirements prescribed in § 113.120 and special requirements prescribed in this section.

Any serial found unsatisfactory by a prescribed test shall not be released.

(a) *Safety tests*—(1) *Test for inactivation.* Bulk or final container samples of completed product shall be tested for live canine distemper virus in canine distemper susceptible ferrets. Each of two such ferrets shall be injected with one dog dose of the vaccine and observed each day for 21 days. If unfavorable reactions attributable to the vaccine occur during the observation period, the serial is unsatisfactory.

(2) *Observation of potency test animals.* The vaccinates used in the potency test in paragraph (b) of this section shall be observed each day prior to challenge. If unfavorable reactions attributable to the vaccine occur during the prechallenge period, the serial is unsatisfactory.

(b) *Potency test.* Bulk or final container samples of completed product shall be tested for potency using 10 canine distemper susceptible dogs (five vaccinates and five controls) as follows:

(1) *Vaccination.* Each of the five vaccinates shall be injected with vaccine as recommended on the label and observed each day for 21 days after the final dose.

(2) *Challenge.* At the end of the observation period, the vaccinates and controls shall be intranasally inoculated at the same time with an equal dose from the same bottle of Snyder Hill canine distemper virus furnished by Veterinary Services and observed each day for an additional 21 days.

(3) *Interpretation.* If all control dogs do not develop typical signs of canine distemper, or lesions of canine distemper, the test is inconclusive and may be repeated: *Provided,* That, if the vaccinates do not remain free of typical signs of canine distemper, the serial is unsatisfactory.

[39 FR 27428, July 29, 1974, as amended at 40 FR 759, Jan. 3, 1975]

§ 113.122 Canine Hepatitis Vaccine, Killed Virus.

Canine Hepatitis Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids or from tissues obtained from an animal that has developed canine hepatitis following inoculation with virulent canine hepatitis virus. Each serial shall meet the applicable general requirements prescribed in § 113.120 and special requirements prescribed in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) *Safety tests.* (1) *Test for inactivation.* Bulk or final container samples of completed product from each serial shall be tested in dogs. Each of two canine hepatitis susceptible dogs shall be inoculated in the anterior chamber of one eye with 0.05 ml of a 4 percent suspension of vaccine. They shall be examined each day for 14 days for corneal opacity characteristic of canine hepatitis. If the eyes do not remain clear, the serial is unsatisfactory.

(2) *Observation of potency test animals.* The dogs in the potency test shall be observed each day prior to challenge. If unfavorable reactions attributable to the product occur, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the vaccine, the test is inconclusive and may be repeated: *Provided,* That, if the test is not repeated, the serial is unsatisfactory.

(b) *Potency test.* Bulk or final container samples of completed product shall be tested for potency using 10 canine hepatitis susceptible dogs (five vaccinates and five controls) as follows:

(1) *Vaccination.* Each of the five vaccinates shall be injected as recommended on the label and observed each day for 21 days.

(2) *Challenge.* At the end of the observation period, the five vaccinates and the five controls shall be inoculated with virulent canine hepatitis virus and observed each day for an additional 10 days.

(3) *Interpretation.* If all control dogs do not develop typical signs of canine hepatitis, the test is inconclusive and may be repeated: *Provided,* That, if the vaccinates do not remain free of typical signs of canine hepatitis, the serial is unsatisfactory.

[39 FR 27428, July 29, 1974]

§ 113.123 Feline Panleukopenia Vaccine, Killed Virus.

Feline Panleukopenia Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing seeds for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed. The Master Seed shall meet the applicable requirements prescribed in § 113.120. Each serial shall meet the applicable general requirements prescribed in § 113.120 and the special requirements for safety and potency provided in this section.

(a) *Safety test.* The vaccinates used in the potency test in paragraph (b) of this section shall be observed each day during the postvaccination observation period. If unfavorable reactions occur which are attributable to the vaccine, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the vaccine, the test is inconclusive and may be repeated: *Provided,* That, if not repeated, the serial is unsatisfactory.

(b) *Potency test—serum-neutralization test.* Bulk or final container samples of completed product shall be tested for potency using five susceptible cats (four vaccinates and one control) as the test animals. Blood samples drawn from each cat shall be individually tested for neutralizing antibody against feline panleukopenia virus to determine susceptibility.

(1) A constant virus-varying serum neutralization test in tissue culture using 100 to 300 $TCID_{50}$ of virus shall be used. Cats shall be considered susceptible if there is no neutralization at a 1:2 final serum dilution.

(2) *Vaccination.* Each of the four vaccinates shall be injected as recommended on the label. If two doses are recommended, the second dose shall be given 7 to 10 days after the first dose and the cats observed each day for 14 to 21 days.

(3) *Serology.* At the end of the postvaccination observation period, a second blood sample shall be obtained from each of the five cats and the serums shall be individually tested for neutralizing antibody against feline panleukopenia virus in the same manner used to determine susceptibility.

(4) *Interpretation of the SN test.* (i) If the control has not remained seronegative at 1:2, the test is inconclusive and may be repeated.

(ii) If at least 3 of the 4 vaccinates in a valid test have not developed titers based upon final serum dilution of at least 1:8, and the remaining vaccinate has not developed a titer of at least 1:4, the serial is unsatisfactory except as provided in paragraphs (b) (5) and (6) of this section.

(5) *Virus-challenge test.* If the results of a valid SN test are unsatisfactory, the vaccinates and the control may be challenged with a virulent feline panleukopenia virus furnished by Veterinary Services and each animal observed each day for an additional 14 days.

(6) *Interpretation of the virus-challenge test.* If the control does not show clinical signs of feline panleukopenia, the test is inconclusive and may be repeated except, that if any of the vaccinates show such signs, the serial is unsatisfactory. Clinical signs of feline panleukopenia shall include a pronounced leukopenia wherein the white blood cell count drops to 4,000 or less per cubic mm or the white cell count drops to less than 25 percent of the normal level established by an average of three or more counts taken prior to challenge.

[39 FR 27428, July 29, 1974, as amended at 40 FR 759, Jan. 3, 1975; 43 FR 41186, Sept. 15, 1978; 43 FR 50162, Oct. 27, 1978; 50 FR 23796, June 6, 1985]

§ 113.124 Mink Enteritis Vaccine, Killed Virus.

Mink Enteritis Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids or tissues obtained from mink that have developed mink enteritis following inoculation with virulent mink enteritis virus. Each serial shall meet the applicable requirements prescribed in § 113.120 and special requirements prescribed in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) *Safety test.* Vaccinates used in the potency test in paragraph (b) of this section shall be observed each day prior to challenge. If unfavorable reactions attributable to the vaccine occur, the serial is unsatisfactory. If unfavorable reactions not attributable to the vaccine occur, the test shall be declared inconclusive and may be repeated: *Provided,* That, if the test is not repeated, the serial is unsatisfactory.

(b) *Potency test.* Bulk or final container samples of completed product shall be tested for potency using 10 mink enteritis susceptible mink (five vaccinates and five controls) as follows:

(1) *Vaccination.* Each of the five vaccinates shall be injected with one dose of vaccine as recommended on the label and observed each day for 14 days.

(2) *Challenge.* Two weeks after the last inoculation, the five vaccinates and the five controls shall be fed mink enteritis virus-laden tissues and observed each day for 12 days.

(3) *Interpretation.* If at least 80 percent of the unvaccinated control mink do not develop enteric symptoms typical of mink enteritis within 12 days, the test is considered inconclusive and may be repeated: *Provided,* That, if at least 80 percent of the vaccinates do not remain well, the serial is unsatisfactory.

[39 FR 27428, July 29, 1974]

§ 113.125 Newcastle Disease Vaccine, Killed Virus.

Newcastle Disease Vaccine (Killed Virus) shall be prepared from virus-bearing tissues or fluids obtained from embryonated chicken eggs or cell cultures. With the exception of § 113.120(c)(2)(iii), each serial shall meet the applicable general requirements prescribed in § 113.120 and special requirements prescribed in this section. A serial found unsatisfactory by a prescribed test shall not be released.

(a) *Safety test.* The prechallenge part of the potency test in paragraph (b) of this section shall constitute a safety test. If unfavorable reactions attributable to the product occur in any of the vaccinates, the serial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur, the test shall be declared inconclusive and may be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(b) *Potency test.* A vaccination-challenge test shall be conducted using susceptible chickens 2 to 6 weeks of age at time of vaccination, properly identified and obtained from the same source and hatch.

(1) Ten or more chickens shall be vaccinated as recommended on the label and kept isolated under observation for at least 14 days.

(2) After at least 14 days post-vaccination, the vaccinates and at least 10 unvaccinated chickens that have been kept isolated as controls shall be challenged with a virulent strain of Newcastle disease virus supplied by or approved by Veterinary Services and the vaccinates observed each day for 14 days.

(3) If at least 90 percent of the controls do not show typical signs of Newcastle disease or die, the test is inconclusive and may be repeated. If at least 90 percent of the vaccinates do not remain normal, the serial is unsatisfactory.

[39 FR 27428, July 29, 1974]

§ 113.126 Wart Vaccine, Killed Virus.

Wart Vaccine, Killed Virus, shall be prepared from virus-bearing epidermal tumors (warts) obtained from a bovine. Each serial shall meet the requirements prescribed in this section and any serial found unsatisfactory by a prescribed test shall not be released.

(a) *Purity.* Final container samples of completed product shall meet the requirements for purity as prescribed in § 113.120 (c) (1) and (3).

(b) *Safety.* Bulk or final container samples of completed product shall meet the requirements for safety as prescribed in § 113.33(b) and § 113.38.

(c) *Formaldehyde content.* Bulk or final container samples of completed product shall meet the requirements for formaldehyde content as prescribed in § 113.120(f).

(d) *Potency and efficacy.* The efficacy of wart vaccine has been demonstrated to the satisfaction of Veterinary Services as being a valuable biological product. The inherent nature of the product precludes the possible development of serial to serial potency tests and none is required: Provided, That,

(1) The vaccine shall be a tissue extract representing at least 10 percent weight to volume suspension of wart tissue; and

(2) The vaccine shall be limited to use in the prevention of warts in cattle. Labeling recommendations shall be in accordance with § 112.7(i).

[40 FR 14084, Mar. 28, 1975, as amended at 40 FR 23989, June 4, 1975; 40 FR 30803, July 23, 1975]

§ 113.127 Encephalomyelitis Vaccine, Eastern and Western, Killed Virus.

Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Except for § 113.120(d), each serial and subserial shall meet the general requirements prescribed in § 113.120 and the requirements prescribed in this section. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(a) *Safety test.* Bulk samples of completed product from each serial shall be tested for encephalomyelitis virus inactivation.

(1) Each of at least ten 6 to 12 hour old chickens shall be injected subcutaneously with 0.5 ml of the product and the chickens observed each day for 10 days.

(2) If unfavorable reactions attributable to the product occur in the chickens during the observation period, the serial is unsatisfactory. If unfavorable reactions not attributable to the product occur, the test is inconclusive and may be repeated: *Provided,* That, if the test is not repeated, the serial is unsatisfactory.

(b) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency in accordance with the two stage test provided in this paragraph. The serological interpretations required in this test shall be made for the Eastern Type fraction and the Western Type fraction independent of each other except that a serial or subserial found unsatisfactory for either fraction shall not be released.

(1) For this test, a guinea pig dose shall be one-half the amount recommended on the label for a horse and shall be administered as recommended for a horse. Each of 10 healthy guinea pigs (vaccinates) shall be injected with two guinea pig doses with an interval of 14 to 21 days between doses. Two additional guinea pigs from the same source shall be held as controls.

(2) Fourteen to 21 days after the second injection, serum samples from each vaccinate and each control shall be tested by the plaque reduction serum neutralization test.

(3) If the control serum samples show a titer greater than 1:2 for either or both fractions, the test is inconclusive for that fraction or fractions, as the case may be, and may be repeated; except that, if 4 or more of the vaccinate serum samples show a titer of less than 1:4 for the Eastern type fraction or less than 1:32 for the Western type fraction, the serial or subserial is unsatisfactory without further testing.

(4) If two or three of the vaccinate serum samples show a titer of less than 1:4 for the Eastern type fraction or less than 1:32 for the Western type fraction or both, the second stage may be used; except, that if a fraction is found to be acceptable by the first stage test, such fraction need not be restested. Otherwise, the second stage shall be conducted in a manner identical to the first stage.

(5) If the second stage is used and 4 or more of the vaccinate serum samples show a titer of less than 1:4 for the Eastern type fraction or less than 1:32 for the Western type fraction, the serial or subserial is unsatisfactory.

(6) The results shall be evaluated according to the following table:

CUMULATIVE TOTALS

Stage	Vaccinates	Failures for acceptance	Failures for rejection
1	10	1 or less	4 or more.
2	20	3 or less	Do.

[39 FR 44714, Dec. 27, 1974, as amended at 40 FR 14084, Mar. 28, 1975; 42 FR 45284, Sept. 9, 1977]

§ 113.128 Avian Encephalomyelitis Vaccine, Killed Virus.

Avian Encephalomyelitis Vaccine (Killed Virus) shall be prepared from virus-bearing tissues or fluids obtained from embryonated chicken eggs. Each serial shall meet the general requirements prescribed in § 113.120 and the requirements prescribed in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) *Safety tests.* (1) The prechallenge part of the potency test prescribed in paragraph (b) of this section shall constitute a safety test. If any of the vaccinates develop clinical signs of disease or die due to causes attributable to the product, the serial is unsatisfactory.

(2) An inactivation test for viable avian encephalomyelitis (AE) virus shall be conducted on each serial. The test shall be conducted using susceptible chicken embryos: *Provided,* That, if a non-embryo adapted virus is used for vaccine production, the test shall be conducted in susceptible chickens.

(i) *Chicken Embryo Test.* Each of 15 or more AE susceptible 5 or 6 day old embryos shall be injected in the yolk sac with 0.2 ml of the vaccine. For a valid test, at least 80 percent of the embryos shall survive for 48 hours post-inoculation (PI). Eleven to 13 days PI, all embryos surviving the 48 hour PI period shall be examined for gross lesions of AE; all these embryos shall be normal or the serial is unsatisfactory. Concurrently, five additional embryos from the same source shall be injected with live AE virus of the production strain to serve as positive controls. At least 4 of the 5 embryos shall show evidence of AE virus infection during the 11 to 13 day PI period or the test shall be considered inconclusive and repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(ii) *Chicken test.* Each of 10 or more AE susceptible 7 day old chickens shall be injected intracerebrally with 0.1 ml vaccine each. The chickens shall be observed each day for 28 days. If any chickens show clinical signs of AE, the serial is unsatisfactory. Concurrently, 5 additional chickens from the same source shall be injected intracerebrally with live AE virus of the production strain to serve as positive controls. At least 4 of the 5 controls shall show evidence of AE virus infection during the observation period or the test shall be inconclusive and may be repeated: *Provided,* That, if the test is not repeated, the serial shall be unsatisfactory.

(b) *Potency test.* Bulk or final container samples of completed product from each serial or one subserial shall be tested. Ten or more AE-susceptible chickens (vaccinates), 4 weeks or older, properly identified and obtained from the same source and hatch, shall be injected as recommended on the label. At least 10 additional AE-susceptible chickens, properly identified and obtained from the same source and hatch shall be kept in isolation as controls.

(1) At least 28 days post-injection, the vaccinates and the controls shall be challenged intramuscularly with a virulent AE virus and the chickens observed each day for 21 days.

(2) If at least 80 percent of the controls do not show clinical signs of or die from AE infection, the test is inconclusive and may be repeated.

(3) If at least 80 percent of the vaccinates do not remain normal, the serial is unsatisfactory.

[39 FR 12958, Dec. 27, 1974, as amended at 40 FR 41088, Sept. 5, 1975]

§ 113.129 Rabies Vaccine, Killed Virus.

Rabies Vaccine (Killed Virus) shall be prepared from virus-bearing cell cultures or nerve tissues obtained from animals that have developed rabies infection following injection with rabies virus. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.120 and the requirements prescribed in this section.

(1) Each lot of Master Seed Virus propagated in tissue or cells of avian origin shall also be tested for extrane-

ous pathogens by procedures prescribed in § 113.37.

(2) Each lot of Master Seed Virus propagated in primary cell cultures of mouse or hamster origin or brain tissues of mouse origin shall be tested for lymphocytic choriomeningitis (LCM) virus by the procedure prescribed in § 113.42. If LCM virus is detected, the Master Seed Virus is unsatisfactory.

(b) The immunogenicity of vaccine prepared with virus at the highest passage from the Master Seed shall be established in each species for which the vaccine is recommended. Tests shall be conducted in accordance with a protocol filed with Veterinary Services before initiation of the tests. The vaccine shall be prepared using methods prescribed in the Outline of Production. If Rabies Vaccine is to be in combination with other fractions, the product to be tested shall include all fractions to be tested.

(1) The preinactivation virus titer shall be established as soon as possible after harvest by at least five separate virus titrations. A mean relative potency value of the vaccine to be used in the host animal potency test shall be established by at least five replicate potency tests conducted in accordance with the NIH Test For Potency in Chapter 33 of "Laboratory Techniques in Rabies," Third Edition (1973), World Health Organization, Geneva. The volumetric method of calculation, as described in this publication, shall be used and the challenge dose shall contain between 5 and 50 LD_{50}. The provisions of "Laboratory Techniques in Rabies," Third Edition (1973), are incorporated by reference and are the minimum standards for achieving compliance with this section.

(2) The dose of vaccine to be used in the immunogenicity test shall be no more than the amount which, on the basis of The NIH Test For Potency, has been diluted to the proposed minimum acceptable potency value.[1]

(3)Test animals shall be uniform and have no neutralizing antibodies to rabies as determined by serum-neutralization (SN) tests.

(i) Twenty-five or more animals shall be used as vaccinates. Each shall be administered a dose of vaccine at the proposed minimum potency level and by the method specified in the Outline of Production.

(ii) Ten or more additional animals shall be held as controls.

(iii) On or about 30, 90, 180, 270, and 365 days postvaccination, all test animals shall be bled and individual serum samples tested for neutralizing antibodies to rabies virus.

(iv) All surviving test animals shall be challenged intramuscularly with virulent rabies virus furnished or approved by Veterinary Services 1 year after vaccinations, except as provided in (b)(4) of this section. The challenged animals shall be observed each day for 90 days as prescribed in § 113.5(b). The brain of each test animal that dies following challenges shall be examined for rabies by the fluorescent antibody test or other method acceptable to Veterinary Services.

(v) Requirements for acceptance in challenge tests shall be death due to rabies in at least 80 percent of the controls while at least 22 of 25 or 26 of 30 or a statistically equivalent number of the vaccinates remain well for a period of 90 days.

(4) When animals of domestic species other than dogs and cats are the test animals, the five vaccinates with the lowest SN titers at each of the last two bleedings may be challenged, except that all vaccinates with SN titers below 1:10 by the mouse SN test or below 1:16 by the rapid fluorescent focus inhibition test at any bleeding shall be challenged at 1 year postvaccination. At least five SN-negative controls of each species shall be challenged at the same time as the vaccinates. All SN titers shall be determined to an endpoint. The unchallenged vaccinates shall be considered protected when evaluated for acceptance as specified in (b)(3)(v) of this section.

(5) An Outline of Production change shall be made before authority for use a new lot of Master Seed Virus shall be granted by Veterinary Services.

(c) If more than 1 year duration of immunity is to be claimed, a duration of immunity test for the additional time shall be contucted and interpreted as prescribed in paragraph (b) of this section for the 1 year test. The test animals shall be monitored serologically at least every 180 days. The time of challenge may be adjusted accordingly.

(d) Test requirements for release: Each serial and each subserial shall meet the general requirements prescribed in § 113.120 and special requirements in this paragraph.

(1) *Purity test.* Primary cell cultures of hamster origin or brain tissues of mouse origin used in vaccine production shall be tested for LCM virus as prescribed in § 113.42. Hamster origin cells shall be disrupted and undiluted cell fluids from each lot shall be tested. Where mouse brains are used in production, at least five mice which have not been injected with rabies virus shall be sacrificed and a 10 percent suspension of brain material shall be prepared and tested.

(2) *Safety tests.* Bulk samples from each serial shall be tested for virus inactivation and safety as follows:

(i) At the end of the inactivation period, each of 20 12 to 16 gram mice shall be injected intracerebrally with 0.03 ml and two rabbits shall be injected into each cerebral hemisphere with 0.25 ml and observed each day for 21 days. The brains of animals dying between the fourth and 21st day post-injection shall be checked for rabies virus. Material from each brain recovered shall be injected into each of five mice and the mice observed each day for 14 days. The fluorescent antibody test or serum neutralization test shall be used to confirm the presence or absence or live rabies virus. If live rabies virus is confirmed, the serial is unsatisfactory unless reprocessed in accordance with § 114.18.

(ii) A test for safety in three young seronegative animals of the most susceptible species for which the vaccine is recommended shall be conducted. Each shall in injected intramuscularly with one recommended dose of vaccine. If unfavorable reactions attributable to the product occur during a 28 day observation period, the serial is unsatisfactory.

(3) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency by tests conducted in accordance with The NIH Test For Potency.[1] The volumetric method of calculation shall be used. The relative potency of each serial shall be at least equal to that used in an approved host animal immunogenicity test.

[39 FR 44715, Dec. 27, 1974, as amended at 42 FR 6794, Feb. 4, 1977; 43 FR 49528, Oct. 24, 1978; 50 FR 20090, May 14, 1985]

§ 113.130 Feline Calicivirus Vaccine, Killed Virus.

Feline Calicivirus Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing seeds for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.120.

(b) The Master Seed shall be tested for chlamydial agents as prescribed in § 113.43.

(c) The immunogenicity of vaccine prepared from the Master Seed in accordance with the Outline of Production shall be established by a method acceptable to Veterinary Services. Vaccine used for this test shall be at the highest passage from the Master Seed and prepared at the minimum preinactivation titer specified in the Outline of Production.

(d) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in § 113.120 and the special requirements provided in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety.* Vaccinates used in the potency test in paragraph (d)(2) of this section shall be observed each day during the prechallenge period. If unfavorable reactions occur, including oral lesions, which are attributable to the vaccine, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the vaccine, the test is inconclusive and may

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[1] See footnote 1 to § 113.129(b).

be repeated. If the test is not repeated, the serial is unsatisfactory.

(2) *Potency.* Bulk or final container samples of completed product shall be treated for potency as follows:

(i) Eight feline calicivirus susceptible cats (five vaccinates and three controls) shall be used as test animals. Throat and nasal swabs shall be collected from each cat and individually tested on susceptible cell cultures for the presence of feline calicivirus. Blood samples shall be drawn and individual serum samples tested for neutralizing antibody. The cats shall be considered suitable for use if all swabs are negative for virus isolation and all serums are negative for calicivirus antibody at the 1:2 final dilution in a 50 percent plaque reduction test or other test of equal sensitivity.

(ii) The five cats used as vaccinates shall be administered one dose of vaccine by the method recommended on the label. If two doses are recommended, the second dose shall be given after the interval recommended on the label.

(iii) Fourteen or more days after the final dose of vaccine, the vaccinates and controls shall each be challenged intranasally with virulent feline calicivirus furnished or approved by Veterinary Services and observed each day for 14 days postchallenge. The rectal temperature of each animal shall be taken and the presence or absence of clinical signs, particularly lesions on the oral mucosa, noted and recorded each day.

(iv) If three of three controls do not show clinical signs of feline calicivirus infection other than fever, the test is inconclusive and may be repeated.

(v) If a significant difference in clinical signs cannot be demonstrated between vaccinates and controls using a scoring system approved by Veterinary Services and prescribed in the Outline of Production, the serial is unsatisfactory.

[50 FR 433, Jan. 4, 1985]

§ 113.131 Feline Rhinotracheitis Vaccine, Killed Virus.

Feline Rhinotracheitis Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing seeds for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.120.

(b) The Master Seed shall be tested for chlamydial agents as prescribed in § 113.43.

(c) The immunogenicity of vaccine prepared from the Master Seed in accordance with the Outline of Production shall be established by a method acceptable to Veterinary Services. Vaccine used for this test shall be at the highest passage from the Master Seed and prepared at the minimum preinactivation titer specified in the Outline of Production.

(d) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in § 113.120 and the special requirements provided in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety test.* Vaccinates used in the potency test in paragraphs (d)(2) of this section shall be observed each day during the prechallenge period. If unfavorable reactions occur which are attributable to the vaccine, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the vaccine, the test is inconclusive and may be repeated. If the test is not repeated, the serial is unsatisfactory.

(2) *Potency test.* Bulk or final container samples of completed product shall be tested for potency as follows:

(i) Eight feline rhinotracheitis susceptible cats (five vaccinates and three controls) shall be used as test animals. Throat and nasal swabs shall be collected from each cat and individually tested on susceptible cell cultures for the presence of feline rhinotracheitis virus. Blood samples shall be drawn and individual serum samples tested for neutralizing antibody. The cats shall be considered suitable for use if all swabs are negative for virus isolation and all serums are negative for rhinotracheitis virus antibody at the 1:2 final dilution in a 50 percent plaque reduction test or other test of equal sensitivity.

(ii) The five cats used as vaccinates shall be administered one dose of vaccine by the method recommended on the label. If two doses are recommended, the second dose shall be given after the interval recommended on the label.

(iii) Fourteen or more days after the final dose of vaccine, the vaccinates and controls shall each be challenged intranasally with virulent feline rhinotracheitis virus furnished or approved by Veterinary Services and observed each day for 14 days postchallenge. The rectal temperature of each animal shall be taken and the presence or absence of clinical signs noted and recorded each day.

(iv) If three of three controls do not show clinical signs of feline rhinotracheitis virus infection other than fever, the test is inconclusive and may be repeated.

(v) If a significant difference in clinical signs cannot be demonstrated between vaccinates and controls using a scoring system approved by Veterinary Services and prescribed in the Outline of Production, the serial is unsatisfactory.

[50 FR 433, Jan. 4, 1985]

§ 113.132 Bursal Disease Vaccine, Killed Virus.

Bursal Disease Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids or embryonated chicken eggs. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing seeds for vaccine production. All serials shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable requirements prescribed in § 113.120.

(b) Each lot of Master Seed shall be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except that, if the test is inconclusive because of a vaccine virus override, the chicken inoculation test prescribed in § 113.36 may be conducted and the virus judged accordingly.

(c) The immunogenicity of vaccine prepared in accordance with the Outline of Production shall be established by a method acceptable to Veterinary Services. Vaccine used for this test shall be at the highest passage from the Master Seed and prepared at the minimum preinactivation titer specified in the Outline of Production. The test shall establish that the vaccine, when used as recommended on the label, is capable of inducing an immune response in dams of sufficient magnitude to provide significant protection to offspring.

(d) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in § 113.120 and the special requirements in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety.* Vaccinates used in the potency test in paragraph (d)(2) of this section shall be observed each day during the prechallenge period. If unfavorable reactions attributable to the vaccine occur, the serial is unsatisfactory. If unfavorable reactions which are not attributable to the vaccine occur, the test is inconclusive and may be repeated. If the test is not repeated, the serial is unsatisfactory.

(2) *Potency.* Bulk or final container samples of completed product from each serial shall be tested for potency using the two-stage potency test provided in this paragraph.

(i) *Vaccinates.* Inject each of 21 susceptible chickens 14 to 28 days of age, properly identified and obtained from the same source and hatch, with one dose of vaccine by the route recommended on the label and observe for at least 21 days.

(ii) *Controls.* Retain at least 10 additional chickens from the same source and hatch as unvaccinated controls.

(iii) *Challenge.* Twenty-one to 28 days postvaccination, challenge 20 vaccinates and 10 controls by eyedrop with a virulent infectious bursal disease virus furnished or approved by Veterinary Services.

(iv) *Postchallenge period.* Four days postchallenge, necropsy all chickens and examine each for gross lesions of bursal disease. For purposes of this test, gross lesions shall include peribursal edema and/or edema and/or macroscopic hemorrhage in the bursal tissue. Vaccinated chickens showing gross lesions shall be counted as failures. If at least 80 percent of the controls do not have gross lesions of bursal disease in a stage of the test, that stage is considered inconclusive and may be repeated. In a valid test, the results shall be evaluated according to the following table:

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total number of failures for—	
			Satisfactory serial	Unsatisfactory serial
1	20	20	3 or less	6 or more.
2	20	40	8 or less	9 or more.

(v) If four or five vaccinates show lesions of bursal disease in the first stage, the second stage may be conducted in a manner identical to the first stage. If the second stage is not conducted, the serial is unsatisfactory.

(vi) If the second stage is used, each serial shall be evaluated according to the second part of the table on the basis of cumulative results.

[50 FR 434, Jan. 4, 1985]

§ 113.133 Pseudorabies Vaccine, Killed Virus.

Pseudorabies Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing seeds for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.120.

(b) The immunogenicity of vaccine prepared from the Master Seed in accordance with the Outline of Production shall be established by a method acceptable to Veterinary Services. Vaccine used for this test shall be at the highest passage from the Master Seed and at the minimum preinactivation titer provided in the Outline of Production.

(c) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in § 113.120 and the special requirements provided in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety.* Vaccinates used in the potency test in paragraph (c)(2) of this section shall be observed each day during the prechallenge period. If unfavorable reactions occur, including neurological signs, which are attributable to the vaccine, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the vaccine, the test is inconclusive and may be repeated. If the test is not repeated, the serial is unsatisfactory.

(2) *Potency.* Bulk or final container samples of completed product shall be tested for potency as follows:

(i) Ten pseudorabies susceptible pigs (five vaccinates and five controls) shall be used as test animals. The animals shall be at the minimal age recommended for vaccination. Blood samples shall be drawn and individual serum samples inactivated and tested for neutralizing antibody.

(ii) A constant virus-varying serum neutralization test in cell culture using 50 to 300 $TCID_{50}$ of virus shall be used. Pigs shall be considered susceptible if there is no neutralization at 1:2 final serum dilution. Other tests of equal sensitivity acceptable to Veterinary Services may be used.

(iii) The five pigs used as vaccinates shall be administered one dose of vaccine as recommended on the label. If two doses are recommended, the second dose shall be given after the interval recommended on the label.

(iv) Fourteen days or more after vaccination, blood samples shall be drawn and individual serum samples inactivated and tested for pseudorabies virus neutralizing antibody by the method used to determine susceptibility.

(v) *Test interpretation.* If the controls have not remained seronegative at 1:2, the test is inconclusive and may be repeated. If at least four of the five vaccinates in a valid test have not developed titers of at least 1:8, and the remaining vaccinate has not developed a titer of at least 1:4, the serial is unsatisfactory, except as provided in paragraph (c)(2)(vi) of this section.

(vi) *Virus challenge test.* If the results of a valid serum neutralization test are unsatisfactory, the vaccinates and controls may be challenged with virulent pseudorabies virus furnished or approved by Veterinary Services. The animals shall be observed each day for 14 days postchallenge. If four of five controls do not develop central nervous system signs or die, the test is inconclusive and may be repeated. In a valid test, if two or more of the vaccinates develop clinical signs or die, the serial is unsatisfactory.

[50 FR 434, Jan. 4, 1985]

§ 113.134 Parvovirus Vaccine, Killed Virus (Canine).

Parvovirus Vaccine, Killed Virus, recommended for use in dogs, shall be prepared from virus-bearing cell culture fluids. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.120.

(b) The immunogenicity of vaccine prepared in accordance with the Outline of Production shall be established as follows:

(1) Twenty-five parvovirus susceptible dogs (20 vaccinates and 5 controls) shall be used as test animals. Blood samples drawn from each dog shall be individually tested for neutralizing antibody against canine parvovirus to determine susceptibility.

A constant virus-varying serum neutralization test in cell culture using 50 to 300 TCID$_{50}$ of virus shall be used. Dogs shall be considered susceptible if there is no neutralization at a 1:2 final serum dilution. Other tests of equal sensitivity acceptable to Veterinary Services may be used.

(2) A viral hemagglutination test or another test acceptable to Veterinary Services shall be used to measure the antigenic content of vaccine produced at the highest passage from the Master Seed before the immunogenicity test is conducted. The 20 dogs used as vaccinates shall be injected with a predetermined dose of vaccine by the method recommended on the label. To confirm the dosage calculations, five replicate tests shall be conducted on a sample of the vaccine used. If two doses are used, five replicate confirming tests shall be conducted on each dose.

(3) Fourteen days or more after the final dose of vaccine, the vaccinates and the controls shall be challenged with virulent canine parvovirus furnished or approved by Veterinary Services and the dogs observed each day for 14 days. Rectal temperature, blood lymphocyte count, and feces for viral detection shall be taken from each dog each day for at least 10 days postchallenge and the presence or absence of clinical signs noted and recorded each day.

(i) The immunogenicity of the vaccine shall be evaluated on the following criteria of infection: temperature >103.4 °F; lymphopenia of >50 percent of prechallenge normal; clinical signs such as diarrhea, mucus in feces, or blood in feces; and viral hemagglutinins at a level of >1:64 in a 1:5 dilution of feces or a test of equal sensitivity. If at least 80 percent of the controls do not show at least three of the four criteria of infection during the observation period, the test is inconclusive and may be repeated.

(ii) If at least 19 of the 20 vaccinates do not survive the observation period without showing any more than one criterion of infection described in subparagraph (3)(i), of this section, the Master Seed is unsatisfactory.

(4) The Master Seed shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only five susceptible dogs (four vaccinates and one control) need to be used in the retest. Suscepti-

bility shall be determined in the manner provided in paragraph (b)(1) of this section.

(i) Each vaccinate shall be injected with a predetermined quantity of vaccine virus as provided in paragraph (b)(2) of this section.

(ii) Fourteen to 21 days after the last vaccination, a second serum sample shall be drawn from each dog and tested for neutralizing antibody to canine parvovirus in the same manner used to determine susceptibility.

(iii) If the control has not remained seronegative at 1:2, the test is inconclusive and may be repeated.

(iv) If three of the four vaccinates in a valid test do not develop titers based upon final serum dilution of at least 1:16, and the remaining vaccinate does not develop a titer of at least 1:8, the Master Seed is unsatisfactory, except as provided in subparagraph (4)(v) of this section.

(v) If the results of a valid SN test are unsatisfactory, the vaccinates and the control may be challenged as provided in paragraph (b)(3) of this section. If at least three of the four criteria of infection are not shown, the test is inconclusive and may be repeated, except that if any of the vaccinates show more than one criterion of infection, the Master Seed is unsatisfactory.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed shall be granted by Veterinary Services.

(c) *Test requirements for release.* Each serial and subserial shall meet the requirements prescribed in § 113.120 and in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Potency.* Bulk or final container samples of completed product shall be tested for antigenic content using the method used in paragraph (b)(2) of this section. To be eligible for release, each serial and each subserial shall have an antigenic content sufficiently greater than that used in the immunogenicity test to assure that, when tested at any time within the expiration period, each serial and subserial shall have an antigenic content equal to the amount used in such immunogenicity test.

(2) *Virus identity.* Bulk or final container samples shall be tested for virus identity by conducting a hemagglutination test using duplicate samples and pretreating one with specific canine parvovirus antibody. If there is not at least an eightfold reduction in hemagglutinating activity, the hemagglutination is considered to be nonspecific and the serial is unsatisfactory.

[50 FR 435, Jan. 4, 1985]

LIVE VIRUS VACCINES

§ 113.135 General requirements for live virus vaccines.

When prescribed in an applicable Standard Requirement or in the filed Outline of Production, a live virus vaccine shall meet the applicable requirements in this section.

(a) *Purity tests.* (1) *Bacteria and fungi.* Final container samples of completed product and comparable samples of each lot of Master Seed Virus shall be tested for bacteria and fungi in accordance with the test provided in § 113.27.

(2) *Mycoplasma.* Final container samples of completed product and comparable samples of each lot of Master Seed Virus shall be tested for mycoplasma in accordance with the test provided in § 113.28.

(3) *Avian Origin Vaccine.* Samples of each lot of Master Seed Virus and bulk pooled material or final container samples from each serial shall also be tested for:

(i) Salmonella contamination as prescribed in § 113.30; and

(ii) Lymphoid leukosis virus contamination as prescribed in § 113.31; and

(iii) Hemagglutinating viruses as prescribed in § 113.34.

(4) *Extraneous viruses.* Each lot of Master Seed Virus used to prepare live virus vaccine recommended for animals other than poultry shall meet the requirements for extraneous viruses as prescribed in § 113.55

(b) *Safety tests.* Samples of each lot of Master Seed Virus and final container samples of completed product from each serial or first subserial of live virus vaccine recommended for animals other than poultry shall be tested for safety in at least one species for which the vaccine is intended using methods prescribed in §§ 113.39, 113.40, 113.41, 113.44, and 113.45 or in a filed Outline of Production. The mouse safety test prescribed in § 113.33(a) shall also be conducted unless the virus or agent in the vaccine is inherently lethal for mice.

(c) *Virus identity test.* At least one of the virus identity tests provided in this paragraph or a suitable identity test prescribed in the filed Outline of Production shall be conducted on the Master Seed Virus and final container samples from each serial or first subserial of biological product.

(1) *Fluorescent antibody test.* The fluorescent antibody test shall be conducted using virus inoculated cells and uninoculated control cells. Cells shall be stained with flourescein conjugated specific antiserum. Flourescence typical of the virus concerned shall be demonstrated in the inoculated cells. The control cells shall remain free of such fluorescence.

(2) *Serum neutralization test.* The serum neutralization test shall be conducted using the constant serum-decreasing virus method with specific antiserum. For positive identification, at least 100 ID_{50} of vaccine virus shall be neutralized by the antiserum.

(d) *Cell Culture Requirements.* If cell cultures are used in the preparation of Master Seed Virus or of the vaccine, primary cells shall meet the requirements prescribed in § 113.51, cell lines shall meet the requirements prescribed in § 113.52, and ingredients of animal origin shall meet the applicable requirements in § 113.53.

(e) *Moisture content.* (1) The maximum moisture content in desiccated vaccines shall be stated in the filed Outline of Production.

(2) Final container samples of completed product from each serial or subserial shall be tested for moisture content in accordance with the test prescribed in § 113.29.

[39 FR 27430, July 29, 1974, as amended at 43 FR 49528, Oct. 24, 1978; 50 FR 1042, Jan. 9, 1985]

§ 113.136 Ovine Ecthyma Vaccine.

Ovine Ecthyma Vaccine shall be prepared from tissue culture fluids or virus-bearing tissues obtained from sheep that have developed ovine ecthyma following inoculation with virulent ovine ecthyma virus. Ovine Ecthyma Vaccine is exempt from the requirements prescribed in § 113.27 and § 113.135 (a), (b), and (c). Each serial shall meet the moisture requirements in § 113.135(e) and the special requirements prescribed in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) *Safety tests.* (1) Bulk or final container samples of completed product from each serial shall be tested for safety as prescribed in § 113.38.

(2) The prechallenge period of the potency test shall constitute a safety test. If unfavorable reactions attributable to the vaccine occur in either of the vaccinates during the observation period, the serial is unsatisfactory.

(b) *Potency test.* Final container samples of completed product from each serial and each subserial shall be tested for potency using susceptible lambs. The vaccine shall be prepared as recommended for use on the label.

(1) Each of two lambs (vaccinates) shall be vaccinated by application of the vaccine to a scarified area on the medial surface of the thigh and observed each day for 14 days.

(2) The immunity of the two vaccinates and one or more unvaccinated lambs (controls) shall be challenged in the same manner as for vaccination, using the opposite thigh.

(3) If typical signs of ovine ecthyma, such as hyperemia, vesicles, and pustules do not develop on the controls during the first 2 weeks following challenge and persist for approximately 30 days, the test is inconclusive and may be repeated.

(4) If the vaccinates do not show a typical immune reaction, the serial is unsatisfactory: *Provided,* That, an initial active reaction with hyperemia which resolves progressively and disappears within 2 weeks, may be characterized as a typical immune reaction.

[39 FR 27430, July 29, 1974]

§ 113.137 Distemper Vaccine—Mink.

Distemper Vaccine—Mink shall be prepared from virus-bearing cell culture fluids. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.135 and the requirements prescribed in this section.

(b) The lot of Master Seed Virus shall be tested for extraneous viruses as follows:

(1) To detect virulent canine distemper virus, each of two distemper susceptible mink or ferrets shall be inoculated with 1 ml of the Master Seed Virus and observed each day for 21 days. If undesirable reactions occur in either test animal, the lot of Master Seed Virus is unsatisfactory.

(2) Master Seed Virus propagated in chicken embryos shall be tested for pathogens by the chicken embryo test prescribed in § 113.37 except lesions typical of distemper virus may be disregarded. If found unsatisfactory, the Master Seed Virus shall not be used.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed Virus shall be established as follows:

(1) At least 25 distemper susceptible mink shall be used as test animals. Blood samples shall be drawn from these animals and individual serum samples tested. The mink shall be considered susceptible if the results are negative at a 1:2 final serum dilution in a varying serum-constant virus neutralization test with less than 500 ID_{50} of canine distemper virus. Other means of insuring susceptibility may be used if prior approval from Veterinary Services is received.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. At least 20 mink shall be vaccinated with a predetermined quantity of vaccine virus and at least 5 additional mink shall be held as unvaccinated controls. To confirm the dosage calculations, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used.

(3) At least twenty-one days post-injection, the immunity of each of the vaccinates and the controls shall be challenged with the same size dose of virulent distemper virus and observed each day for 21 days.

(i) If at least 80 percent of the controls do not die or show severe signs of distemper, the test is inconclusive and may be repeated.

(ii) If at least 19 of 20, 27 of 30, or 36 of 40 of the vaccinates do not survive without showing clinical signs of distemper during the observation period, the Master Seed Virus is unsatisfactory.

(4) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only five vaccinates and five controls need to be used in the retest; *Provided*, That five of the five vaccinates and at least four of the controls shall meet the criteria prescribed in paragraph (c)(3) of this section.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be authorized by Veterinary Services.

(d) Test requirements for release: Each serial and subserial shall meet the general requirements prescribed in § 113.135 and the requirements in this paragraph. Final container samples of completed product shall be tested. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Mink safety test.* Each of 2 mink shall be vaccinated with the equivalent of 10 doses of vaccine rehydrated with sterile diluent and administered in the manner recommended on the label. The mink shall be observed each day for 21 days. If unfavorable reactions attributable to the product occur in either of the mink during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur, the test shall be declared inconclusive and may be repeat-

ed: *Provided*, That if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

(2) *Potency Test.* An in vitro potency test shall be conducted. To be eligible for release, each serial and subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that, when tested at any time within the expiration period, each serial and subserial shall have a virus titer $10^{0.7}$ greater than that used in such immunogenicity test when tested by the method used in paragraph (c)(2) of this section.

[40 FR 53000, Nov. 14, 1975, as amended at 48 FR 33471, July 22, 1983]

§ 113.138 Bluetongue Vaccine.

Bluetongue Vaccine shall be prepared from virus-bearing cell culture fluids. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing the seeds for vaccine production. All serials of vaccine shall be prepared from the first through the tenth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.135 and the requirements in this section.

(b) Each lot of Master Seed shall be tested for transmissibility and reversion to virulence in sheep using a method acceptable to Veterinary Services. If reversion to virulence is demonstrated, the Master Seed is unsatisfactory.

(c) Each lot of Master Seed used for vaccine production shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed shall be established as follows:

(1) Twenty-five lambs, susceptible to the bluetongue virus serotype contained in the vaccine, shall be used as test animals (20 vaccinates and 5 controls). Blood samples shall be drawn from these animals and individual serums tested. A lamb shall be considered susceptible if there is no neutralization at a 1:2 final serum dilution in a constant virus varying serum neutralization test with 60 to 300 $TCID_{50}$ of bluetongue virus or another method acceptable to Veterinary Services.

(2) A geometric mean titer of the vaccine produced from the highest passage from the Master Seed shall be established before the immunogenicity test is conducted. The 20 lambs to be used as vaccinates shall be administered a predetermined quantity of vaccine virus by the method recommended on the label. To confirm the virus dosage administered, five replicate virus titrations shall be conducted on a sample of the vaccine used.

(3) At least once during the period of 14 to 18 days postvaccination, individual serum samples shall be collected from each of the vaccinates and tested for virus neutralizing antibody using the 60 to 300 $TCID_{50}$ of bluetongue virus.

(4) Twenty-one to twenty-eight days postvaccination the vaccinates and the controls shall each be challenged with virulent bluetongue virus and observed for 14 days. The rectal temperature of each animal shall be taken and recorded for 17 consecutive days beginning 3 days prechallenge. The presence or absence of lesions or other clinical signs of bluetongue noted and recorded on each of 14 consecutive days postchallenge.

(i) If at least four of the five controls do not show clinical signs of bluetongue and a temperature rise of 3 °F or higher over the prechallenge mean temperature, the test shall be considered inconclusive and may be repeated.

(ii) If at least 19 of the 20 vaccinates tested as prescribed in paragraph (c)(3) of this section do not have bluetongue neutralizing antibody titers of 1:4 final serum dilution or higher, or if more than one of the vaccinates shows a temperature rise of 3 °F or higher than its prechallenge mean temperature for 2 or more days, or if more than one of the vaccinates exhibits clinical signs of bluetongue, the Master Seed is unsatisfactory.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed shall be granted by Veterinary Services.

(6) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only five vaccinates and five controls need be used in the

retest: *Provided*, That five of five vaccinates and at least four of the five controls shall meet the criteria prescribed in paragraphs (c)(4) of this section.

(d) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in § 113.135 and the requirements in this paragraph. Final container samples of completed product shall be tested. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety test.* The mouse safety test prescribed in 113.33(a) and the lamb safety test prescribed in 113.45 shall be conducted.

(2) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in such immunogenicity test.

[50 FR 23796, June 6, 1985]

§ 113.139 Feline Panleukopenia Vaccine.

Feline Panleukopenia Vaccine shall be prepared from virus-bearing cell culture fluids. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable general requirements prescribed in § 113.135 and the requirements prescribed in this section.

(b) The lot of Master Seed Virus shall be tested for other agents as follows:

(1) To detect virulent feline panleukopenia virus or virulent mink enteritis virus, each of two feline panleukopenia susceptible cats, as determined by the criteria prescribed in paragraph (c)(1) of this section, shall be injected subcutaneously with the equivalent of one cat dose each and the cats observed each day for 21 days. If either or both cats show signs of disease or reduced white blood cell counts below 50 percent of the normal level established by an average of three or more counts taken prior to injection, the Master Seed Virus is unsatisfactory.

(2) To detect chlamydial agents, the Master Seed Virus shall be tested as prescribed in § 113.43.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed Virus shall be established as follows:

(1) Twenty-five feline panleukopenia susceptible cats shall be used as test animals (20 vaccinates and 5 controls). Blood samples drawn from each cat shall be individually tested for neutralizing antibody against feline panleukopenia virus to determine susceptibility.

(i) A constant virus-carrying serum neutralization test in tissue culture using 100 to 300 $TCID_{50}$ of virus shall be used.

(ii) Cats shall be considered susceptible if there is no neutralization at a 1:2 final serum dilution.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. The 20 cats used as vaccinates shall be injected with a predetermined quantity of vaccine virus and the remaining five cats held as uninjected controls. To confirm the dosage calculations, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used.

(3) Fourteen days post-injection, the vaccinates and the controls shall be challenged with virulent feline panleukopenia virus furnished by Veterinary Services and the cats observed each day for 14 days.

(i) If at least 80 percent of the controls do not show clinical signs of feline panleukopenia during the observation period, the test is inconclusive and may be repeated. Clinical signs of feline panleukopenia shall include a pronounced leukopenia wherein the white cell count drops to 4,000 or less per cubic mm, or the white cell count drops to less than 25 percent of the normal level established by an average of three or more counts taken prior to challenge.

(ii) If at least 19 of the 20 vaccinates do not survive the observation period without showing clinical signs of feline panleukopenia as described in paragraph (c)(3)(i), of this section, the Master Seed Virus is unsatisfactory.

(4) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Ten susceptible cats (8 vaccinates and 2 controls) shall be used in the retest. Susceptibility shall be determined in the manner provided in paragraph (c)(1) of this section.

(i) Each vaccinate shall be injected with a predetermined quantity of vaccine virus as provided in paragraph (c)(2) of this section.

(ii) Fourteen to twenty-one days postvaccination, a second serum sample shall be drawn from each cat and tested for neutralizing antibody to feline panleukopenia virus in the same manner used to determine susceptibility.

(iii) If the two controls have not remained seronegative at 1:2, the test is inconclusive and may be repeated.

(iv) If at least 6 of the 8 vaccinates in a valid test do not develop titers based upon final serum dilution of at least 1:8, and the remaining vaccinates do not develop titers of at least 1:4, the Master Seed Virus is unsatisfactory except as provided in paragraph (c)(4)(v) of this section.

(v) If the results of a valid SN test are unsatisfactory, the vaccinates and the controls may be challenged as provided in paragraph (c)(3) of this section. If 100 percent of the controls do not show clinical signs of feline panleukopenia, the test is inconclusive and may be repeated except, that, if any of the vaccinates show such signs, the Master Seed Virus is unsatisfactory.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) *Test requirements for release.* Each serial and subserial shall meet the requirements prescribed in § 113.135 and in this paragraph. Final container samples of completed product shall be tested. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety Test.* The mouse safety test prescribed in § 113.33(a) and the cat safety test prescribed in § 113.39 shall be conducted.

(i) Each of two healthy cats shall be injected with 10 cat doses by the method recommended on the label and the cats observed each day for 14 days.

(ii) If unfavorable reactions attributable to the biological product occur during the observation period, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the product, the test shall be declared inconclusive and repeated: *Provided,* That, if not repeated, the serial shall be unsatisfactory.

(2) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in such immunogenicity test but not less than $10^{2.5}$ $TCID_{50}$ per dose.

[39 FR 44716, Dec. 27, 1974, as amended at 40 FR 53378, Nov. 18, 1975; 43 FR 25078, June 9, 1978; 43 FR 41186, Sept. 15, 1978; 44 FR 58900, Oct. 12, 1979; 48 FR 33471, July 22, 1983]

§ 113.140 Canine Hepatitis Vaccine.

Canine Hepatitis Vaccine shall be prepared from virus bearing cell culture fluids. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used in preparing the production seed virus for vaccine production. All serials shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.135 and the requirements prescribed in this section.

(b) The lot of Master Seed Virus shall be tested for other viral agents as follows:

(1) To detect wild infectious canine hepatitis virus, each of two canine hepatitis susceptible dogs or foxes shall be injected intravenously with 2.0 ml of the seed virus and observed each day for 21 days. If clinical signs or deaths due to infectious canine hepatitis occur in either test animal during the observation period the seed virus is unsatisfactory.

(2) To detect virulent canine distemper virus, each of 2 ferrets known to be susceptible to canine distemper virus shall be injected with 1.0 ml of the seed virus and observed each day for 21 days. If clinical signs or deaths due to canine distemper occur in either test animal during the observation period, the seed virus is unsatisfactory.

(3) To detect canine distemper virus, 10 Leighton tubes containing coverslips or equally suitable cell culture vessels shall be seeded with any type cell that is susceptible to canine distemper virus. When the cell growth is satisfactory, each of five vessels shall be inoculated with 0.2 ml mixture of seed virus and antiserum (equal volumes of virus and monospecific high titer infectious canine hepatitis antiserum). Seven to ten days later, all the cell cultures shall be stained with a canine distemper specific fluorescent antibody. If all the cell cultures are not negative for specific viral staining, the seed virus is unsatisfactory. Positive virus controls shall be included.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed Virus being tested shall be established as follows:

(1) Twenty-five canine hepatitis susceptible dogs shall be used as test animals (20 vaccinates and five controls). Blood samples shall be drawn from these animals and individual serum samples tested. The dogs shall be considered susceptible if the results are negative at a 1:2 final serum dilution in a varying serum-constant virus neutralization test with less than 500 TCID$_{50}$ of infectious canine hepatitis virus.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. The 20 dogs to be used as vaccinates shall be injected with a predetermined quantity of vaccine virus and the remaining five dogs held as uninjected controls. To confirm the dosage calculations, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used.

(3) Not less than fourteen days postinjection, the vaccinates and the controls shall each be challenged intravenously with virulent infectious canine hepatitis virus and observed each day for 14 days.

(i) If at least four of the five controls do not die and the survivor, if any, does not show clinical signs of infectious canine hepatitis and infectious canine hepatitis virus is not isolated from such survivor, the test is inconclusive and may be repeated.

(ii) If at least 19 of the 20 vaccinates do not survive without showing clinical signs of infectious canine hepatitis during the observation period, the Master Seed Virus is unsatisfactory.

(4) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Ten susceptible dogs (8 vaccinates and 2 controls) shall be used in the retest. Susceptibility shall be determined in the manner provided in paragraph (c)(1) of this section.

(i) Each vaccinate shall be injected with a predetermined quantity of vaccine virus as provided in paragraph (c)(2) of this section.

(ii) Fourteen to twenty-one days postvaccination, a second serum sample shall be drawn from each dog and tested for neutralizing antibody to canine hepatitis virus in the same manner used to determine susceptibility.

(iii) If the two controls have not remained seronegative at 1:2, the test is inconclusive and may be repeated.

(iv) If at least 6 of the 8 vaccinates in a valid test do not develop titers of at least 1:10 based upon final serum dilution, the Master Seed Virus is unsatisfactory except as provided in paragraph (c)(4)(v) of this section.

(v) If the results of a valid SN test are unsatisfactory, the vaccinates and the controls may be challenged as provided in paragraph (c)(3) of this section. If 100 percent of the controls do not show clinical signs of canine hepatitis, the test is inconclusive and may be repeated except, that, if any of the vaccinates show such signs, the Master Seed Virus is unsatisfactory.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) Test requirements for release: Each serial and subserial shall meet the general requirements prescribed in § 113.135 and special requirements in this paragraph. Final container samples of completed product shall be tested. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) The dog safety test prescribed in § 113.40 and the mouse safety test prescribed in § 113.33(a) shall be conducted.

(2) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in such immunogenicity test but not less than $10^{2.5}$ ID_{50} per dose.

[39 FR 44717, Dec. 27, 1974, as amended at 40 FR 23989, June 4, 1975; 40 FR 41088, Sept. 5, 1975; 43 FR 25078, June 9, 1978; 43 FR 41187, Sept. 15, 1978; 43 FR 49528, Oct. 24, 1978; 48 FR 33471, July 22, 1983]

§ 113.141 Canine Distemper Vaccine (Ferret Avirulent).

Canine Distemper Vaccine (Ferret Avirulent) shall be prepared from virus-bearing cell culture fluids or embryonated chicken eggs. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.135 and the requirements prescribed in this section.

(b) The lot of Master Seed Virus shall be tested for other viral agents as follows:

(1) To detect wild canine distemper virus, each of two canine distemper susceptible ferrets shall be injected with a sample of the Master Seed Virus equivalent to the amount of virus to be used in one dog dose and observed each day for 21 days. If undesirable reactions occur in either ferret, the lot of Master Seed Virus is unsatisfactory.

(2) Master Seed Virus propagated in chicken embryos shall be tested for pathogens by the chicken embryo test prescribed in § 113.37. If found unsatisfactory, the Master Seed Virus shall not be used.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed Virus shall be established as follows:

(1) Twenty-five canine distemper susceptible dogs shall be used as test animals (20 vaccinates and five controls). Blood samples shall be drawn from these animals and individual serum samples tested. The dogs shall be considered susceptible if the results are negative at a 1:2 final serum dilution in a varying serum-constant virus neutralization test with less than 500 ID_{50} of canine distemper virus.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. The 20 dogs used as vaccinates shall be injected with a predetermined quantity of vaccine virus and the remaining five dogs held as uninjected controls. To confirm the dosage calculations, five

replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used.

(3) At least twenty-one days post-injection, the vaccinates and the controls shall each be challenged intracerebrally with the same size dose of Snyder Hill canine distemper virus furnished by Veterinary Services and observed each day for 21 days.

(i) If at least four of the five controls do not die and the survivor, if any, does not show clinical signs of canine distemper and canine distemper virus isolated from such survivor, the test is inconclusive and may be repeated.

(ii) If at least 19 of the 20 vaccinates do not survive without showing clinical signs of canine distemper during the observation period, the Master Seed Virus is unsatisfactory.

(4) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Ten susceptible dogs (8 vaccinates and 2 controls) shall be used in the retest. Susceptibility shall be determined in the manner provided in paragraph (c)(1) of this section.

(i) Each vaccinate shall be injected with a predetermined quantity of vaccine virus as provided in paragraph (c)(2) of this section.

(ii) Fourteen to twenty-one days postvaccination, a second serum sample shall be drawn from each dog and tested for neutralizing antibody to canine distemper virus in the same manner used to determine susceptibility.

(iii) If the two controls have not remained seronegative at 1:2, the test is inconclusive and may be repeated.

(iv) If at least 6 of the 8 vaccinates in a valid test do not develop titers of at least 1:50 based upon final serum dilution, the Master Seed Virus is unsatisfactory except as provided in paragraph (c)(4)(v) of this section.

(v) If the results of a valid SN test are unsatisfactory, the vaccinates and the controls may be challenged as provided in paragraph (c)(3) of this section. If 100 percent of the controls do not show clinical signs of canine distempter, the test is inconclusive and may be repeated except, that, if any of the vaccinates show such signs, the Master Seed Virus is unsatisfactory.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) Test requirements for release: Each serial and subserial shall meet the general requirements prescribed in § 113.135 and the requirements in this paragraph. Final container samples of completed product shall be tested. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety tests.* The dog safety test prescribed in § 113.40 and the mouse safety test prescribed in § 113.33(a) shall be conducted.

(2) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in such immunogenicity test but not less than $10^{2.5}$ ID_{50} per dose.

[39 FR 44717, Dec. 27, 1974, as amended at 40 FR 41089, Sept. 5, 1975; 43 FR 25078, June 9, 1978; 43 FR 41187, Sept. 15, 1978; 43 FR 49528, Oct. 24, 1978; 43 FR 50162, Oct. 27, 1978; 48 FR 33471, July 22, 1983]

§ 113.142 Canine Distemper Vaccine (Ferret Virulent).

Canine Distemper Vaccine (Ferret Virulent) shall be prepared from virus-bearing cell culture fluids or virus-bearing tissues obtained from ferrets that have developed canine distemper following inoculation with canine distemper virus. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be produced from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.135 and the special requirements prescribed in this section: *Provided*, That, the virus identity test in paragraphs (a) (1) and (2) of this section may be conducted instead of either test prescribed in § 113.135(c).

(1) Dogs used in the safety test in § 113.40 shall be bled prior to injection and 14 to 21 days post-injection and individual serum samples prepared. When tested by a serum-neutralization method (constant virus, 100 to 500 EID_{50}, varying serum), each sample shall show serological conversion by a four-fold increase in antibodies.

(i) Chorioallantoic membranes of five 6 to 8 day old chicken embryos shall each be inoculated with 0.2 ml of the virus-antiserum mixture and a like number similarly inoculated with 0.2 ml of the virus-diluent mixture.

(ii) Absence of evidence of virus on the membranes inoculated with virus-serum mixtures demonstrates specific neutralization, provided evidence of virus on the membranes inoculated with the virus-diluent mixture is demonstrated.

(2) Ferret virulence shall be demonstrated by the virus titration conducted in susceptible ferrets.

(b) The lot of Master Seed Virus shall be tested for other viral contaminants as prescribed in § 113.55.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed Virus shall be established as follows:

(1) Twenty-five canine distemper susceptible dogs shall be used as test animals (20 vaccinates and five controls). Blood samples shall be drawn from these animals and individual serum samples tested. The dogs shall be considered susceptible if the results are negative at a 1:2 final serum dilution in varying serum-constant virus neutralization test with less than 500 ID_{50} of canine distemper virus.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established by a ferret injection method before the immunogenicity test is conducted. The 20 dogs used as vaccinates shall be injected with a predetermined quantity of vaccine virus and the remaining five dogs held as uninjected controls. To confirm the dosage calculations, a replicate virus titration shall be conducted on a sample of the vaccine virus dilution used. A satisfactory titration shall have at least one dilution having between 50 percent and 100 percent positives and at least one dilution having between 50 percent and 0 percent positives. At least 10 ferrets shall be used per dilution.

(3) Twenty-one days post-injection, the vaccinates and the controls shall each be challenged intracerebrally with the same size dose of Snyder Hill canine distemper virus furnished by Veterinary Services. The test animal shall be observed each day for 21 days.

(i) If at least four of the five controls do not die and the survivor, if any, does not show clinical signs of canine distemper and canine distemper virus isolated from such survivor, the test is inconclusive and may be repeated.

(ii) If at least 19 of the 20 vaccinates do not survive without showing clinical signs of disease during an observation period of 21 days, the Master Seed Virus is unsatisfactory.

(4) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only five vaccinates and five controls need to be used in the retest; *Provided*, That five of five vaccinates and at least four of the controls shall meet the criteria prescribed in paragraph (c)(3) of this section.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) Test requirements for release: Each serial and subserial shall meet the general requirements prescribed in § 113.135, except that the virus identity test prescribed in paragraphs (a) (1) and (2) of this section may be used instead of tests prescribed in § 113.135(c), and the requirements in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Purity test.* Primary dog kidney cells which have been tested as pre-

scribed in § 113.51 covering an area equal to two glass or plastic flasks (150 cm^2 total) and Vero cells covering an area equal to one glass or plastic flasks (75 cm^2 total) shall be used for testing for extraneous viral agents as follows:

(i) Harvesting bulk untreated material consisting of ferret spleen suspension or ferret kidney tissue culture fluids or both shall be inoculated onto the monolayers in amounts equal to five percent of the amount of maintenance media in the flasks. The inoculum shall be allowed to absorb for 2 hours and then be removed.

(ii) The cells shall be washed with phosphate buffered saline (PBS) and maintenance media added. Twenty-four hours later the media may be changed if there is evidence of cytotoxicity from the inoculum.

(iii) All cultures shall be observed each day for 14 days after inoculation for cytopathic effect (CPE). Subcultures shall be conducted if necessary.

(iv) If there is no CPE, one of the primary dog kidney cell monolayers shall be washed in several changes of PBS and tested by successive hemadsorption tests using 0.2 percent human 0, guinea pig, and chickens erythrocytes. After each appropriate incubation period, the cells shall be observed for hemadsorption indicating presence of a virus.

(v) The second primary dog kidney monolayer shall be subcultured in Leighton tubes with coverslips for appropriate fluorescent antibody tests.

(vi) If extraneous viral agents are detected, the serial or subserial shall not be released.

(2) *Safety tests.* Final container samples of completed product from each serial shall be tested for safety in dogs as prescribed in § 113.40 and in mice as prescribed in § 113.33(a).

(3) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer. To be eligible for release, each serial and subserial shall have a virus titer sufficiently greater than the virus dose used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in such immunogenicity test when tested by the ferret injection method.

[39 FR 44718, Dec. 27, 1974, as amended at 40 FR 41089, Sept. 5, 1975; 43 FR 49528, Oct. 24, 1978; 48 FR 33471, July 22, 1983]

§ 113.143 Encephalomyelitis Vaccine, Venezuelan.

Encephalomyelitis Vaccine, Venezuelan, shall be prepared from virus-bearing cell culture fluids. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing seeds for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.135 except (b), and the requirements prescribed in this section.

(b) Each lot of Master Seed shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed shall be established as follows:

(1) Tests conducted by the Department have established that horses having Venezuelan equine encephalomyelitis antibody titers of 1:20 by the hemagglutination-inhibition (HI) method or 1:40 by the serum neutralization (SN) method were immune to challenge with virulent virus. The immunogenicity test is based on the demonstration of a serological response of at least that magnitude following vaccination of serologically negative horses.

(2) At least 22 horses (20 vaccinates and 2 controls), susceptible to Venezuelan equine encephalomyelitis, shall be used as test animals. Blood samples shall be taken from each horse and the serums individually tested for neutralizing antibody. Horses shall be considered susceptible if there is no neutralization at a 1:2 final serum dilution in a constant virus-varying serum neutralization test using 60 to 300 $TCID_{50}$ of Venezuelan equine encephalomyelitis virus.

(3) A geometric mean titer of the vaccine produced from the highest passage of the Master Seed shall be established using a method acceptable to Veterinary Services before the immun-

ogenicity test is conducted. The 20 horses used as vaccinates shall be injected with a predetermined quantity of vaccine virus by the method to be recommended on the label. To confirm the dosage administered, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used.

(4) Twenty-one to twenty-eight days postvaccination, blood samples shall be drawn from all test animals. For a valid test, the controls shall remain seronegative at 1:2 final serum dilution. In a valid test, if at least 19 of 20 vaccinates do not have antibody titers of at least 1:20 in a haemagglutination-inhibition test or at least 1:40 in a serum neutralization test, the Master Seed is unsatisfactory.

(5) The Master Seed shall be retested for immunogenicity in 3 years unless use of the lot is discontinued. Only five vaccinates and two controls need to be used in the retest: *Provided*, That five of five vaccinates and the two controls shall meet the criteria in paragraph (b)(4) of this section.

(6) An Outline of Production change shall be made before authority for use of a new lot of Master Seed shall be granted by Veterinary Services.

(c) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in § 113.135 and special requirements in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety test.* The mouse safety test prescribed in § 113.33(b) shall be conducted.

(2) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the method in paragraph (b)(3) of this section. To be eligible for release, each serial and subserial shall have a virus titer sufficiently greater than the titer of the vaccine used in the immunogenicity test prescribed in paragraph (b) of this section to assure that, when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in the immunogenicity test, but not less than $10^{2.5}$ $TCID_{50}$ per dose.

[50 FR 23797, June 6, 1985]

§ 113.144 Bovine Parainfluenza₃ Vaccine.

Bovine Parainfluenza₃ Vaccine shall be produced from virus-bearing cell culture fluids. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be prepared from the first through the tenth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable general requirements prescribed in § 113.135.

(b) Each lot of Master Seed Virus shall meet the special requirements prescribed in this section.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed Virus shall be established as follows:

(1) Twenty-five bovine parainfluenza₃ susceptible calves shall be used as test animals (20 vaccinates and five controls). Blood samples shall be drawn from these animals and individual serums tested. Also, nasal specimens shall be collected for virus isolation attempts. The calves shall be considered susceptible if:

(i) The results are negative at a 1:2 final serum dilution in a varying serum constant virus neutralization test with less than 500 $TCID_{50}$ of bovine parainfluenza₃ virus; and

(ii) Shall be negative to bovine parainfluenza₃ virus isolation attempts from the nasal specimens on the day of injection.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. The 20 calves to be used as vaccinates shall be injected with a predetermined quantity of vaccine virus and the remaining five calves held as uninjected controls. To confirm the dosage calculation, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used.

(3) The vaccinates and controls shall be examined for clinical signs of respiratory disease and the body tempera-

ture taken and recorded on each of the first 14 consecutive days post-injection. The vaccinates shall be bled on day 6±2 days post-injection.

(4) Three to four weeks post-vaccination, all calves shall be bled for serum antibodies and nasal specimens shall be collected for PI$_3$ virus isolation. On the same day, all vaccinates and controls shall be given acceptable challenge PI$_3$ virus titrating at least $10^{7.0}$ TCID$_{50}$ per ml and the animals observed for 14 days. Two ml of the challenge virus shall be instilled in each nostril or shall be inhaled as an aerosol suspension. Upon request, challenge virus and instructions shall be furnished by Veterinary Services.

(5) Each animal shall be examined for clinical signs of respiratory disease and the body temperature recorded on each of the 14 consecutive days of the post-challenge observation period. Each day for at least the first 10 days post-challenge, nasal specimens for virus isolation attempts shall be taken. All animals shall be bled on day 6±2 days post-challenge, and all animals shall be bled at least once 14 to 28 days post-challenge for serum antibody studies.

(6) Satisfactory Test Criteria:

(i) All virus isolations attempts shall be by culture and at least one subculture in PI$_3$ susceptible cells for a total of at least 14 days.

(ii) Two to four weeks post-vaccination, at least 19 of the 20 vaccinates shall have PI$_3$ neutralizing antibody titers of at least 1:4 and all five controls shall be negative at 1:2 dilution. None of the post-vaccination serums collected from the vaccinates on day 6±2 days shall reveal serum neutralization antibody titers of 1:32 or greater based upon final dilution.

(iii) Satisfactory resistance to challenge by vaccinates shall be determined by a significant difference between virus isolation rates from vaccinates and controls. The virus neutralization titers of post-challenge serums and respiratory symptoms and temperatures from all animals shall be considered in the evaluation of the test validity.

(7) Designated animal alternates for test animals showing anamnestic antibody responses (titers 1:32 or greater) on day 6 serums may be included in the study under the following provisions:

(i) No more than five alternates shall be allowed for the vaccinates and no more than two for the controls.

(ii) Alternates shall be subject to all requirements outlined for the animals for which they are alternates.

(iii) Antibody values from alternate animals may be used only to replace values from up to and including five vaccinates which develop antibody of 1:32 or greater by day 6±2 days post-vaccination or up to and including two controls which develop antibody titers of 1:32 or greater by day 6±2 days post-challenge.

(8) A sequential test procedure may be used in lieu of the 20 calf requirement. A beta value of .05 and a tolerance level of .78 shall be required.

(9) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only five vaccinates and five controls need to be used in the retest; *Provided*, That five of five vaccinates and at least four of the controls shall meet the criteria prescribed in paragraph (c)(6) of this section.

(10) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) Test requirements for release: Each serial and subserial shall meet the applicable general requirements prescribed in § 113.135 and the requirements in this paragraph. Final container samples of completed product shall be tested except as prescribed in paragraph (d)(1) of this section. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Purity test.* The test for Brucella contamination prescribed in § 113.32 shall be conducted on each batch of primary cells intended for production use.

(2) *Safety test.* The mouse safety test prescribed in § 113.33(a) and the calf safety test prescribed in § 113.41 shall be conducted.

(3) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using

the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer per dose sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in the immunogenicity test but not less than $10^{2.5}$ $TCID_{50}$ per dose.

[39 FR 44719, Dec. 27, 1974, as amended at 40 FR 41089, Sept. 5, 1975; 43 FR 49529, Oct. 24, 1978; 48 FR 33472, July 22, 1983]

§ 113.145 Bovine Rhinotracheitis Vaccine.

Bovine Rhinotracheitis Vaccine shall be prepared from virus-bearing cell culture fluids. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be prepared from the first through the tenth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable general requirements prescribed in § 113.135.

(b) Each lot of Master Seed Virus shall meet the special requirements prescribed in this section.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed Virus shall be established as follows:

(1) Twenty-five infectious bovine rhinotracheitis susceptible calves shall be used as test animals (20 vaccinates and five controls). Blood samples shall be drawn from these animals and individual serums tested. The calves shall be considered susceptible if the results are negative at a 1:2 final serum dilution by the virus plaque reduction method.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. The 20 calves to be used as vaccinates shall be injected with a predetermined quantity of vaccine virus and the remaining five calves held as uninjected controls. To confirm the dosage calculations, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used.

(3) At least once during a period of 14 to 28 days post-vaccination, individual serum samples shall be collected for virus-neutralization tests from each of the vaccinates. The test virus shall be 100 to 500 $TCID_{50}$ bovine rhinotracheitis virus. Results shall be used in making a determination as prescribed in paragraph (c)(6) of this section.

(4) The vaccinates and the controls shall each be challenged with virulent infectious bovine rhinotracheitis virus and observed for 14 days. The rectal temperature of each animal shall be taken and the presence or absence of respiratory or other clinical signs of bovine rhinotracheitis noted and recorded on each of the 14 consecutive days.

(5) If at least four of the five controls do not show clinical signs of infectious bovine rhinotracheitis and a marked temperature rise to 104.5° F. or higher post-challenge, the test shall be considered inconclusive and may be repeated.

(6) If less than 19 of the post-injection serum samples tested as prescribed in paragraph (c)(3) of this section show neutralization in all tubes of the 1:2 final serum dilution, or if more than one of the vaccinates show a temperature of 103.5° F. or higher for 2 or more days, or if more than one of the vaccinates exhibit respiratory or other clinical signs of infectious bovine rhinotracheitis, or both, the Master Seed Virus is unsatisfactory.

(7) A sequential test procedure may be used in lieu of the 20 calf requirement. A beta value of .05 and a tolerance level of .78 shall be required.

(8) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only five vaccinates and five controls need to be used in the retest; *Provided*, That five of five vaccinates and at least four of the five controls shall meet the criteria prescribed in paragraphs (c)(5) and (6) of this section.

(9) An outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) Test requirements for release: Each serial and subserial shall meet the applicable general requirements prescribed in § 113.135 and the requirements in this paragraph. Final container samples of completed product shall be tested except as prescribed in paragraph (d)(1) of this section. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Purity test.* The test for Brucella contamination prescribed in § 113.32 shall be conducted on each batch of primary cells intended for production use.

(2) *Safety test.* The mouse safety test prescribed in § 113.33(a) and the calf safety test prescribed in § 113.41 shall be conducted.

(3) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer per dose sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in the immunogenicity test but not less than $10^{2.5}$ $TCID_{50}$ per dose.

[39 FR 44720, Dec. 27, 1974, as amended at 40 FR 20067, May 8, 1975; 40 FR 23989, June 4, 1975; 40 FR 41089, Sept. 5, 1975; 43 FR 49529, Oct. 24, 1978; 48 FR 33472, July 22, 1983]

§ 113.146 Bovine Virus Diarrhea Vaccine.

Bovine Virus Diarrhea Vaccine shall be prepared from virus-bearing cell culture fluids. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be prepared from the first through the tenth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable general requirements prescribed in § 113.135.

(b) Each lot of Master Seed Virus shall meet the special requirements prescribed in this section.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed Virus shall be established as follows:

(1) Twenty-five bovine virus diarrhea susceptible calves shall be used as test animals (20 vaccinates and five controls). Blood samples shall be drawn from these animals and individuals serum samples tested. The calves shall be considered susceptible to bovine virus diarrhea virus infection if the results are negative at a 1:2 final serum dilution in a varying serum-constant virus neutralization test with less than 500 $TCID_{50}$ of bovine virus diarrhea virus.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. The 20 calves to be used as vaccinates shall be injected with a predetermined quantity of vaccine virus and the remaining five calves held as uninjected controls. To confirm the dosage calculations, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used.

(3) At least once during a period 14 to 28 days post-vaccination, individual serium samples shall be collected for virus-neutralization tests from each of the vaccinates. The test virus shall be less than 500 $TCID_{50}$ of bovine virus diarrhea virus. The white cell count for all vaccinates and controls shall be established at least 3 days just before challenge. Results shall be used in making a determination as prescribed in paragraph (c)(5) of this section.

(4) The vaccinates and the controls shall each be challenged with virulent bovine virus diarrhea virus and observed for 14 consecutive days. The white cell count shall be determined daily on each animal from the second through the eighth day post-challenge. If leukopenia does not develop in at least four of the five controls as

compared with the vaccinates, the test shall be considered inconclusive and may be repeated.

(5) If less than 19 of the post-injection serum samples, tested as prescribed in paragraph (c)(3) of this section, show neutralization in all tubes of the 1:8 dilution; or if more than one of the vaccinates exhibits respiratory or other clinical signs of bovine virus diarrhea post-challenge; or both, the Master Seed Virus is unsatisfactory.

(6) A sequential test procedure may be used in lieu of the 20 calf requirement. A beta value of .05 and a tolerance level of .78 shall be required.

(7) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only five vaccinates and five controls need to be used in the retest; *Provided*, That five of five vaccinates and at least four of the five controls shall meet the criteria prescribed in paragraphs (c)(4) and (c)(5) of this section.

(8) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) Test requirements for release: Each serial and subserial shall meet the applicable general requirements prescribed in § 113.135 and the requirements in this paragraph. Final container samples of completed product shall be tested except as prescribed in paragraph (d)(1) of this section. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Purity test.* The test for Brucella contamination prescribed in § 113.32 shall be conducted on each batch of primary cells intended for production use.

(2) *Safety test.* The mouse safety test prescribed in § 113.33(a) and the calf safety test prescribed in § 113.41 shall be conducted.

(3) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer per dose sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have virus titer of $10^{0.7}$ greater than that used in the immunogenicity test but not less than $10^{2.5}$ TCID$_{50}$ per dose.

[39 FR 44721, Dec. 27, 1974, as amended at 40 FR 20067, May 8, 1975; 40 FR 41089, Sept. 5, 1975; 43 FR 49529, Oct. 24, 1978; 48 FR 33472, July 22, 1983]

§ 113.147 Rabies Vaccine.

Rabies Vaccine shall be prepared from virus-bearing cell cultures or embryonated chicken eggs. Only Master Seed Virus which has been established as pure, safe and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable general requirements prescribed in § 113.135.

(1) Each lot of Master Seed Virus shall meet the special requirements prescribed in this section.

(2) Each lot of Master Seed Virus propagated in tissues or cells of avian origin shall be tested for pathogens by procedures prescribed in § 113.37.

(3) Each lot of Master Seed Virus propagated in primary cell cultures of mouse or hamster origin or brain tissues of mouse origin shall be tested for lymphocytic choriomeningitis (LCM) virus by the procedure prescribed in § 113.42. If OCM virus is detected, the Master Seed Virus is unsatisfactory.

(4) The Master Seed Virus shall be studied in each species of carnivore or domesticated wild animal for which the vaccine is specifically recommended to attempt to determine the fate of the vaccine virus. Results shall be considered in evaluating safety of vaccine virus.

(i) Obtain at least 10 unvaccinated animals, negative at 1:2 final serum dilution, of each species in which tests will be conducted. Divide each species into two groups of five animals.

(ii) For each species of animal, inject one group of five animals intramuscularly. Infiltrate a major nerve and the surrounding tissue in each of the five animals in the other group. Use 1.0 ml of high titer virus for each method of administration.

(iii) Observe all animals for signs of rabies until scheduled time to sacrifice. If animals show definite symptoms, sacrifice and check regional lymph nodes, brain, salivary glands, and kidney for rabies virus by injection of suckling mice (not more than 7 days of age). Tissues may be held frozen at −70° C. until suckling mice are available. Inject each mouse in one litter intracerebrally with 0.02 ml of a ground tissue suspension from each organ. Observe mice each day for 21 days. If any mice die, determine if the deaths were due to rabies virus in the brain by a fluorescent antibody test.

(iv) Sacrifice animals that do not show signs of rabies according to the following schedule and check regional lymph nodes, brain, salivary glands, and kidney in suckling mice.

Route of injection	Days after injection	Number of animals
Intramuscularly	15, 20, 25, 30, 35	1 each day.
Intraneurally	3, 6, 9, 15, 30	1 each day.

(5) Each lot of Master Seed Virus shall be tested for safety in at least 10 unvaccinated serologically negative animals of each domestic species for which the vaccine is recommended.

(i) Each group of 10 animals shall be divided into 2 groups of 5 animals. For each species, inject one group intramuscularly with 10 doses of high titer virus.

(ii) Infiltrate a major nerve of each of the animals in the other group of 5 with 10 doses of the same high titer virus. For all species except dogs and cats, multiple injections along the cervical spine in the proximity to the nerve trunks emerging from the spinal cord may be used: *Provided*, That a 1-dose volume shall be injected into each of four or more sites bilaterally.

(iii) Observe all animals each day for 90 days.

(iv) If any animals show clinical signs of rabies, sacrifice the animal and check appropriate brain tissue for rabies virus by the fluorescent antibody test and by mouse injection.

(v) If rabies is confirmed, the lot of Master Seed Virus is unsatisfactory.

(b) The immunogenicity of vaccine prepared with virus at the highest passage of the Master Seed shall be established in each species for which the vaccine is recommended. Tests shall be conducted in accordance with a protocol filed with Veterinary Services before initiation of the tests. The vaccine shall be prepared using methods prescribed in the Outline of Production. If Rabies Vaccine is to be in combination with other fractions, the product tested shall include all fractions to be recommended.

(1) A geometric mean virus titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. To confirm the dosage calculations, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used.

(2) The dose of vaccine to be used in the immunogenicity test shall be no more than the amount of rehydrated vaccine which, on the basis of previous titrations, has been diluted to the proposed minimum acceptable virus titer.

(3) Test animals shall be uniform and have no neutralizing antibodies to rabies as determined by serum-neutralization (SN) tests.

(i) Twenty-five or more animals shall be used as vaccinates. Each shall be injected intramuscularly at one site in the thigh with a dose of vaccine at the proposed minimum virus titer as specified in the filed Outline of Production.

(ii) Ten or more additional animals shall be held as controls.

(iii) On or about days 30, 90, 180, 270, and 365 postvaccination, all animals shall be bled and individual serums tested for neutralizing antibodies to rabies virus.

(iv) All surviving test animals of each species shall be challenged intramuscularly with virulent rabies virus furnished or approved by Veterinary Services 1 year after vaccination, except as provided in paragraphs (b)(4), (b)(5), and (b)(6), of this section. The challenged animals shall be observed each day for 90 days as prescribed in § 113.5(b). The brain of each test animal that dies following challenge shall be examined for rabies by the fluorescent antibody test or other method acceptable to Veterinary Services.

(v) Requirements for acceptance in challenge tests shall be death due to rabies in at least 80 percent of controls while at least 22 of 25 or 26 of 30 or a statistically equivalent number of the vaccinates remain well for a period of 90 days.

(4) When animals of domestic species other than dogs and cats are the test animals, the five vaccinates with the lowest SN titers at each of the last two bleedings may be challenged, except that all vaccinates with SN titers below 1:10 by mouse SN test or below 1:16 by the rapid fluorescent focus inhibition test at any bleeding shall be challenged at 1 year postvaccination. At least five SN-negative controls of each species shall be challenged at the same time as the vaccinates. All SN titers shall be determined to an endpoint. The unchallenged vaccinates shall be considered protected when evaluated for acceptance as specified in (b)(3)(v) of this section.

(5) The Master Seed Virus shall be retested for immunogenicity in 3 years and each 5 years thereafter unless use of the lot previously tested is discontinued. Only five vaccinates and five controls need to be used in the retest and the retest may be limited to serological response at 1 year after vaccination of the vaccinates if such response is equal to or greater than that in the original immunogenicity test and all controls remain negative. If the SN response is not satisfactory, the vaccinates and controls may be challenged. To be satisfactory, at least 4 of the 5 controls shall die of rabies and 5 of the 5 vaccinates remain well for a period of 90 days.

(6) The repeat immunogenicity tests may be terminated after 90 day SN tests if at least 10 vaccinates and at least 5 controls of each species are used and the test dose of vaccine contains the minimum acceptable virus titer throughout dating.

(i) If the 10 vaccinates have SN titers equal to or greater than the 90 day SN titers of the vaccinates in the initial immunogenicity test, the Master Seed Virus is satisfactory.

(ii) If the 10 vaccinates do not have acceptable SN titers, each vaccinate and each control shall be challenged at 1 year with virulent rabies street virus and observed for 90 days.

(iii) If at least 80 percent of the controls do not show signs of rabies during the observation period, the test is invalid and shall be repeated.

(iv) If more than 10 percent of the vaccinates show signs of rabies, the Master Seed Virus is unsatisfactory.

(7) An outline of Production change shall be made before authority for use of a new lot of Master Virus shall be granted by veterinary services.

(c) If more than 1 year duration of immunity is to be claimed, a duration of immunity test for the additional time shall be conducted and interpreted as prescribed in paragraph (b) of this section for the 1 year test. The test animals shall be monitored serologically at least every 180 days. The time of challenge may be adjusted accordingly.

(d) Test requirements for release: Each serial and each subserial shall meet the general requirements prescribed in § 113.135 and special requirements in this paragraph.

(1) *Purity and safety tests.* Final container samples of completed product from each serial or one subserial shall be tested.

(i) The test for pathogens, prescribed in § 113.37 shall be conducted on each serial or one subserial of avian origin. If necessary, neutralize the rabies virus with specific rabies antiserum.

(ii) A test for safety in three young seronegative animals of the most susceptible species for which the vaccine is recommended shall be conducted. Each shall be injected intramuscularly with 10 recommended doses of vaccine. If unfavorable reactions attributable to the product occur during a 28 day observation period, the serial is unsatisfactory.

(iii) If primary cell cultures of hamster origin or of mouse origin are used vaccine roduction, they shall be tested for LCM virus as prescribed in § 113.42. The cells shall be disrupted and undiluted cell fluids from each lot shall be tested.

(2) *Virus titrations.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (b)(1) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently higher than the titer of the vaccine virus used in paragraph (b) of this section to assure that, when tested at any time within the expiration period, each serial and subserial shall have a virus titer equal to or greater than that used in the immunogenicity test.

(3) Young adult mice, each weighing 14 to 16 grams, shall be used as test animals when the virus in vaccine prepared with a low egg passage Flury Strain or high cell passage Street Alabama Dufferin Strain (HCP SAD) of rabies virus is titrated. At least 10 mice for each dilution shall be used.

(i) At least 10 mice shall be used for each dilution. Each shall be injected intracerebrally with 0.03 ml.

(ii) The injected young adult mice shall be observed each day for 14 days except when testing vaccines made with HCP SAD strain of rabies virus, in which case, the mice shall be observed each day for 21 days. Deaths and paralysis occurring subsequent to the fourth day post-injection shall be noted and the LD$_{50}$ titer calculated by the Reed and Muench Method.

(iii) Virus titer requirements for release and at expiration date shall be determined for each vaccine on the basis of data available: *Provided,* That, the lowest titer permitted at expiration date when determined by this test shall be $10^{3.0}$ LD$_{50}$ per 0.03 ml.

(4) Suckling mice, 6 days of age or younger, shall be used as test animals when virus in vaccine prepared with a high egg passage Flury Strain of rabies virus is titrated.

(i) Six to twelve mice shall be used for each dilution. Each shall be injected intracerebrally with 0.02 ml.

(ii) The injected suckling mice shall be observed each day for 21 days. Deaths and paralysis occurring subsequent to the fourth day post-injection shall be noted and the LD$_{50}$ titer calculated by the Reed and Muench Method; and

(iii) Virus titer requirements for release and at expiration date shall be determined for each vaccine on the basis of data available: *Provided,* That, the lowest titer permitted at expiration date when determined by this test shall be $10^{3.0}$ LD$_{50}$ per 0.02 ml.

[39 FR 44721, Dec. 27, 1974, as amended at 40 FR 20067, May 8, 1975; 42 FR 6795, Feb. 4, 1977; 43 FR 49529, Oct. 24, 1978; 50 FR 20090, May 14, 1985; 50 FR 23797, June 6, 1985]

§ 113.148 Measles Vaccine.

Measles Vaccine shall be prepared from virus-bearing cell culture fluids. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable general requirements prescribed in § 113.135. Each lot of Master Seed Virus shall meet the special requirements prescribed in this section.

(b) To detect virulent canine distemper virus, each of two canine distemper susceptible ferrets shall be injected with a sample of the Master Seed Virus equivalent to the amount of virus to be used in one dog dose and observed each day for 21 days. If undesirable reactions occur in either ferret, the lot of Master Seed Virus is unsatisfactory.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed Virus shall be established as follows:

(1) Twenty-five dogs, less than 12 weeks of age and free of measles antibody, shall be used as test animals (20 vaccinates and five controls). Blood samples shall be drawn from these animals and individual serum samples tested. The dogs shall be considered susceptible if the results are negative at a 1:2 final serum dilution in a varying serum-constant virus neutralization test with less than 500 ID$_{50}$ of measles virus.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. Twenty dogs shall be vaccinated with a predetermined quantity of vaccine virus and the remaining five dogs held as unvaccinated controls. To confirm the dosage calculations, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used.

(3) On the day of challenge, serum samples shall be obtained from each vaccinate and individually tested for antibody against canine distemper virus. For a valid test, each vaccinate shall be negative at a 1:4 final serum dilution in varying serum-constant virus neutralization test using less than 500 ID_{50} of canine distemper virus.

(4) At least 21 days postinoculation, the immunity of the vaccinates and controls shall be challenged by exposure to a uniform dose of aerosolized virulent canine distemper virus. All test dogs shall be observed daily for 21 days postchallenge.

(i) If at least 4 of the 5 controls do not die or show signs of distemper, including a temperature of 104.0° F. or higher and at least 15 percent weight loss, the test is inconclusive and may be repeated.

(ii) If at least 19 of the 20 vaccinates do not survive without showing a temperature of 104.0° F. or higher and a weight loss exceeding 15 percent after day 8 postchallenge, the Master Seed Virus is unsatisfactory.

(5) When approved in advance by Veterinary Services, a sequential test procedure may be used in lieu of the 20 dog requirement. A beta value of 0.05 and a tolerance level of 0.78 shall be required.

(6) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only five vaccinates and five controls need to be used in the retest; *Provided*, That five of five vaccinates and at least four of the controls shall meet the criteria prescribed in this section.

(7) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) Test requirements for release: Each serial and subserial shall meet the general requirements prescribed in § 113.135 and the requirements in this paragraph. Final container samples of completed product shall be tested. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety tests.* The dog safety test prescribed in § 113.40 and the mouse safety test prescribed in § 113.33(a) shall be conducted.

(2) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of the vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in the immunogenicity test but not less than $10^{2.5}$ ID_{50} per dose.

[40 FR 53001, Nov. 14, 1975, as amended at 43 FR 49529, Oct. 24, 1978; 48 FR 33472, July 22, 1983]

§ 113.149 Feline Calicivirus Vaccine.

Feline Calicivirus Vaccine shall be prepared from virus-bearing cell culture fluids. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable general requirements prescribed in § 113.135.

(b) The Master Seed Virus shall be tested for chlamydial agents as prescribed in § 113.43.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed Virus shall be established as follows:

(1) Thirty feline calicivirus susceptible cats shall be used as test animals (20 vaccinates and 10 controls). Throat swabs shall be collected from each cat and individually tested on susceptible cell cultures for the presence of feline calicivirus. Blood samples shall be drawn and individual serum samples tested. The cats shall be considered suitable for use if all swabs are negative for virus isolation and if all serums are negative for calicivirus antibody at the 1:2 final dilution in a 50 percent plaque reduction test or other SN test of equal sensitivity.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. The 20 cats used as vaccinates shall be administered a predetermined quantity of vaccine virus by the method to be recommended on the label and the remaining 10 cats shall be held as controls. To confirm the dosage calculations, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used. If two doses are used, five replicate confirming titrations shall be conducted on each dose.

(3) Twenty-one or more days after the final dose of vaccine, the vaccinates and controls shall each be challenged intranasally with a minimum of 100,000 $TCID_{50}$ or plaque forming units of virulent feline calicivirus furnished or approved by Veterinary Services and observed each day for 14 days postchallenge. The rectal temperature of each animal shall be taken and the presence or absence of clinical signs, particularly lesions on the oral mucosa, noted and recorded each day.

(i) If less than 8 of 10 controls show clinical signs of feline calicivirus infection other than fever, the test is inconclusive and may be repeated.

(ii) If a significant difference in clinical signs cannot be demonstrated between vaccinates and controls using a scoring system approved by Veterinary Services and prescribed in the Outline of Production, the Master Seed Virus is unsatisfactory.

(4) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Either 10 vaccinates and 6 controls or 5 vaccinates and 3 controls shall be used in the retest.

(i) If less than 5 of 6 or 3 of 3 of the controls in the retest show clinical signs of feline calicivirus infection other than fever, the test is inconclusive and may be repeated.

(ii) A significant difference in clinical signs shall be demonstrated between vaccinates and controls in a valid test as prescribed in paragraph (c)(3)(ii) of this section.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) *Test requirements for release.* Each serial and subserial shall meet the requirements prescribed in § 113.135 and in this paragraph. Final container samples of completed product shall be tested. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety test.* The mouse safety test prescribed in § 113.33(a) and the cat safety test prescribed in § 113.39(b) shall be conducted.

(2) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in the immunogenicity test but not less than $10^{2.5}$ $TCID_{50}$ or plaque forming units per dose.

[44 FR 58899, Oct. 12, 1979; 44 FR 63083, Nov. 2, 1979, as amended at 48 FR 33472, July 22, 1983]

§ 113.150 Feline Rhinotracheitis Vaccine.

Feline Rinotracheitis Vaccine shall be prepared from virus-bearing cell culture fluids. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable general requirements prescribed in § 113.135.

(b) The Master Seed Virus shall be tested for chlamydial agents as prescribed in § 113.43.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity. The selected virus dose from the lot of Master Seed Virus shall be established as follows:

(1) Thirty feline rhinotracheitis susceptible cats shall be used as test animals (20 vaccinates and 10 controls). Throat swabs shall be collected from each cat and individually tested on susceptible cell cultures for the presence of feline rhinotracheitis virus. Blood samples shall be drawn and individual serum samples tested. The cats shall be considered suitable for use if all swabs are negative for virus isolation and if all serums are negative for feline rhinotracheitis virus antibody at the 1:2 final dilution in a 50 percent plaque reduction test or other SN test of equal sensitivity.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. The 20 cats used as vaccinates shall be administered a predetermined quantity of vaccine virus by the method to be recommended on the label and the remaining 10 cats shall be held as controls. To confirm the dosage calculations, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used. If two doses are used, five replicate confirming titrations shall be conducted on each dose.

(3) Twenty-one or more days after the final dose of vaccine, the vaccinates and controls shall each be challenged intranasally with a minimum of 100,000 TCID$_{50}$ or plaque forming units of virulent feline rhinotracheitis virus furnished or approved by Veterinary Services and observed each day for 14 days post-challenge. The rectal temperature of each animal shall be taken and the presence of respiratory or other clinical signs of feline rhinotracheitis noted and recorded each day.

(i) If less than 8 of 10 controls show clinical signs of feline rhinotracheitis infection other than fever, the test is inconclusive and may be repeated.

(ii) If a significant difference in clinical signs cannot be demonstrated between vaccinates and controls using a scoring system approved by Veterinary Services and prescribed in the Outline of Production, the Master Seed Virus is unsatisfactory.

(4) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Either 10 vaccinates and 6 controls or 5 vaccinates and 3 controls shall be used in the retest.

(i) If less than 5 of 6 or 3 of 3 of the controls in the retest show clinical signs of feline rhinotracheitis infection other than fever, the test is inconclusive and may be repeated.

(ii) A significant difference in clinical signs shall be demonstrated between vaccinates and controls in a valid test as prescribed in paragraph (c)(3)(ii) of this section.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) *Test requirements for release.* Each serial and subserial shall meet the requirements prescribed in § 113.135 and in this paragraph. Final container samples of completed product shall be tested. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety test.* The mouse safety test prescribed in § 113.33(a) and the cat safety test prescribed in § 113.39(b) shall be conducted.

(2) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a

virus titer of $10^{0.7}$ greater than that used in the immunogenicity test but not less than $10^{2.5}$ $TCID_{50}$ or plaque forming units per dose.

[44 FR 58899, Oct. 12, 1979, as amended at 48 FR 33472, July 22, 1983]

§ 113.151 Canine Parainfluenza Vaccine.

Canine Parainfluenza Vaccine shall be prepared from virus-bearing cell culture fluids. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing seeds for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.135 and the requirements in this section.

(b) Each lot of Master Seed shall be tested for immunogenicity. The selected virus dose shall be established as follows:

(1) Twenty-five canine parainfluenza susceptible dogs (20 vaccinates and 5 controls) shall be used as test animals. Nasal swabs shall be collected from each dog on the day the first dose of vaccine is administered and individually tested on susceptible cell cultures for the presence of canine parainfluenza virus. Blood samples shall also be drawn and individual serum samples tested for neutralizing antibody. Dogs shall be considered susceptible if all swabs are negative for virus isolation and if all serums are negative for canine parainfluenza antibody at a 1:2 final dilution in a constant virus-varying serum neutralization test using 50 to 300 $TCID_{50}$ of canine parainfluenza virus.

(2) A geometric mean titer of vaccine produced at the highest passage from the Master Seed shall be established before the immunogenicity test is conducted. The 20 dogs used as vaccinates shall be administered a predetermined quantity of vaccine virus. Five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used to confirm the dosage administered. If two doses are used, five replicate confirming titrations shall be conducted on each dose.

(3) Three to 4 weeks after the final dose of vaccine, all dogs shall be bled for serum antibodies and nasal swabs shall be collected for canine parainfluenza virus isolation. On the same day, all vaccinates and controls shall be challenged with canine parainfluenza virus furnished or approved by Veterinary Services.

(4) The rectal temperature of each dog shall be taken and the presence of respiratory or other clinical signs of canine parainfluenza virus infection noted and recorded each day for 14 consecutive days postchallenge. Nasal swabs shall be collected from each dog each day for at least 10 consecutive days postchallenge. Individual swabs shall be tested for virus isolation by culture in canine parainfluenza virus susceptible cells for at least 7 days. Results shall be evaluated according to the following criteria:

(i) If five of five controls have not remained seronegative at a final serum dilution of 1:2 during the prechallenge period, the test is inconclusive and may be repeated.

(ii) If more than one vaccinate shows febrile response, respiratory or other clinical signs of canine parainfluenza virus infection; or, if less than 19 of 20 vaccinates show serum neutralization titers of 1:4 or greater; or, if there is not a significant reduction in virus isolation rate in vaccinates when compared with controls, the Master Seed is unsatisfactory.

(5) The Master Seed shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only five vaccinates and five controls need to be used in the retest: *Provided*, That five of five vaccinates and five of five controls shall meet the criteria prescribed in paragraph (b)(4) of this section.

(6) An Outline of Production change shall be made before authority for use of a new lot of Master Seed shall be granted by Veterinary Services.

(c) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in § 113.135 and the requirements in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Virus titer requirements.* Final container samples of completed prod-

uct shall be tested for virus titer using the titration method used in paragraph (b)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (b) of this section to assure that, when tested at any time within the expiration period, each serial and subserial shall have a virus titer at least $10^{0.7}$ greater than that used in the immunogenicity test but not less than $10^{2.5}$ $TCID_{50}$ per dose.

[50 FR 436, Jan. 4, 1985]

§ 113.152 Parvovirus Vaccine (Canine).

Parvovirus Vaccine recommended for use in dogs shall be prepared from virus-bearing cell culture fluids. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing seeds for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.135 and the requirements in this section.

(b) The Master Seed shall be tested for reversion to virulence in dogs using a method acceptable to Veterinary Services. If a significant increase in virulence is seen within five backpassages, the Master Seed is unsatisfactory.

(c) Each lot of Master Seed shall be tested for immunogenicity. The selected virus dose shall be established as follows:

(1) Twenty-five canine parvovirus susceptible dogs (20 vaccinates and 5 controls) shall be used as test animals. Blood samples drawn from each dog shall be individually tested for neutralizing antibody against canine parvovirus to determine susceptibility. Dogs shall be considered susceptible if there is no neutralization at a 1:2 final serum dilution in a constant virus-varying serum neutralization test in cell culture using 50 to 300 $TCID_{50}$ of canine parvovirus.

(2) A geometric mean titer of the vaccine produced at the highest passage from the Master Seed shall be established before the immunogenicity test is conducted. The 20 dogs used as vaccinates shall be administered a predetermined quantity of vaccine virus by the method recommended on the label. To confirm the dosage calculations, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used. If two doses are used, five replicate confirming titrations shall be conducted on each dose.

(3) Fourteen days or more after the final dose of vaccine the vaccinates and the controls shall be challenged with virulent canine parvovirus furnished or approved by Veterinary Services and the dogs observed each day for 14 days. Rectal temperature, blood lymphocyte count, and feces for viral detection shall be taken from each dog each day for at least 10 days postchallenge and the presence or absence of clinical signs noted and recorded each day.

(i) The immunogenicity of the Master Seed shall be evaluated on the following criteria of infection: temperature >103.4 °F; lymphopenia of >50 percent of prechallenge normal; clinical signs such as diarrhea, mucus in feces, or blood in feces; and viral hemagglutinins at a level of >1:64 in a 1:5 dilution of feces or a test of equal sensitivity. If at least 80 percent of the controls do not show at least three of the four criteria of infection during the observation period, the test is inconclusive and may be repeated.

(ii) If at least 19 of the 20 vaccinates do not survive the observation period without showing more than one criterion of infection described in subparagraph (c)(3)(i), of this section, the Master Seed is unsatisfactory.

(4) The Master Seed shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Five susceptible dogs (four vaccinates and one control) may be used in the retest. Susceptibility shall be determined in the manner provided in paragraph (c)(1) of this section.

(i) Each vaccinate shall be administered a predetermined quantity of vaccine virus as provided in paragraph (c)(2) of this section.

(ii) Fourteen to 21 days after the last vaccination, a second serum sample shall be drawn from each dog and tested for neutralizing antibody to canine parvovirus in the same manner used to determine susceptibility.

(iii) If the control has not remained seronegative at 1:2, the test is inconclusive and may be repeated.

(iv) If three of the four vaccinates in a valid test do not develop titers of at least 1:16 final serum dilution, and the remaining vaccinate does not develop a titer of at least 1:8, the Master Seed is unsatisfactory, except as provided in paragraph (c)(4)(v) of this section.

(v) If the results of a valid SN test are unsatisfactory, the vaccinates and the control may be challenged as provided in paragraph (c)(3) of this section. If at least three of the four criteria of infection are not shown in the control dog, the test is inconclusive and may be repeated, except that if any of the vaccinates show more than one criterion of infection, the Master Seed is unsatisfactory.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed shall be granted by Veterinary Services.

(d) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in § 113.135 and the requirements in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of vaccine used in the immunogencity test in paragraph (c) of this section to assure that, when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in the immunogenicity test, but not less than $10^{2.5}$ ID_{50} per dose.

[50 FR 436, Jan. 4, 1985]

§ 113.153 Pseudorabies Vaccine.

Pseudorabies Vaccine shall be prepared from virus-bearing cell culture fluids. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing seeds for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.135 and the requirements in this section.

(b) Each lot of Master Seed shall be tested for immunogenicity. The selected virus dose shall be established as follows:

(1) Twenty-five pseudorabies susceptible pigs (20 vaccinates and 5 controls) of the youngest age for which the vaccine is recommended, shall be used as test animals. Blood samples shall be taken from each pig and the serums inactivated and individually tested for neutralizing antibody against pseudorabies virus. Pigs shall be considered susceptible if there is no neutralization at a 1:2 final serum dilution in a constant virus-varying serum neutralization test using 50 to 300 $TCID_{50}$ pseudorabies virus.

(2) A geometric mean titer of the vaccine produced at the highest passage from the Master Seed shall be established before the immunogenicty test is conducted. The 20 pigs used as vaccinates shall be administered a predetermined quantity of vaccine virus by the method recommended on the label. To confirm the dosage administered, five replicate virus titrations shall be conducted on a sample of the vaccine virus dilution used.

(3) Fourteen to 28 days postvaccination, the vaccinates and controls shall be challenged with virulent pseudorabies virus furnished or approved by Veterinary Services and observed each day for 14 days.

(i) If at least four of the five controls do not develop severe central nervous system signs or die, the test is inconclusive and may be repeated.

(ii) If at least 19 of the 20 vaccinates in a valid test do not remain free of signs of pseudorabies, the Master Seed is unsatisfactory.

(4) The Master Seed shall be retested for immunogenicity in 3 years unless use of the lot is discontinued. Only five vaccinates and five controls need to be used in the retest. Suscepti-

bility and age requirements shall be as provided in paragraph (b)(1) of this section.

(ii) Fourteen to 28 days postvaccination, a blood sample shall be taken from each pig and the serum inactivated and tested for neutralizing antibody to pseudorabies virus by the same method used to determine susceptibility.

(iii) If the five controls have not remained seronegative at 1:2, the test is inconclusive and may be repeated.

(iv) If at least four of the five vaccinates in a valid test have not developed titers of 1:8 final serum dilution or greater and the remaining vaccinate a titer of 1:4 or greater, the Master Seed is unsatisfactory, except as provided in paragraph (b)(4)(v).

(v) If the results of a valid neutralization test are unsatisfactory, the vaccinates and controls may be challenged as provided in paragraph (b)(3) of this section. If at least four of five controls do not develop severe central nervous system signs or die, the test is inconclusive and may be repeated. If all five of the vaccinates in a valid test do not remain free of signs of pseudorabies, the Master Seed is unsatisfactory.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed shall be granted by Veterinary Services.

(c) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in § 113.135 and the requirements in this paragraph.

(2) *Virus titer requirements.* Final container samples of completed product shall be titrated by the method used in paragraph (b)(2) of this section. To be eligible for release, each serial and subserial shall have a virus titer sufficiently greater than the titer of the vaccine used in the immunogenicity test prescribed in paragraph (b) of this section to assure that, when tested at any time within the expiration period, each serial and subserial shall have a virus titer at least $10.^{0.7}$ greater than that used in the immunogenicity test, but not less than $10^{2.5}$ $TCID_{50}$ per dose.

[50 FR 437, Jan. 4, 1985]

§§ 113.154—113.159 [Reserved]

§ 113.160 Avian Encephalomyelitis Vaccine.

Avian Encephalomyelitis Vaccine shall be prepared from virus-bearing tissues or fluids from embryonated chicken eggs. Only Master Seed Virus which has been established as pure, safe, and immunogenic in accordance with the requirements in paragraphs (a), (b), and (c) of this section shall be used for preparing the production seed virus for vaccine production. All serials shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.135 and the requirements prescribed in this section.

(b) Each lot of Master Seed Virus shall be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except that, if the test is inconclusive because of a vaccine virus override, the test may be repeated and if the repeat test is inconclusive for the same reason, the chicken inoculation test prescribed in § 113.36 may be conducted and the virus judged accordingly.

(c) Each lot of Master Seed Virus shall be tested for immunogenicity and the selected virus dose to be used shall be established as follows:

(1) Avian encephalomyelitis susceptible chickens, all of the same age (eight weeks or older) and from the same source, shall be used. Twenty or more chickens shall be used as vaccinates for each method of administration recommended on the label. Ten additional chickens of the same age and from the same source shall be held as unvaccinated controls.

(2) A geometric mean titer of the vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. Each vaccinate shall receive a predetermined quantity of vaccine virus. Five replicate virus titrations shall be conducted on an aliquot of the vaccine virus to confirm the amount of virus administered to each chicken used in the test. At least three appropriate (not to exceed ten-

fold) dilutions shall be used and the test conducted as follows:

(i) For each dilution, inoculate at least 10 embryos, 5 or 6 days old, in the yolk sac with 0.2 ml each. Twenty similar embryos obtained from the same source shall be kept as uninoculated negative controls. Disregard all deaths during the first 48 hours post-inoculation.

(ii) Eggs for each dilution shall be kept in separate containers and allowed to hatch. Sufficient precaution shall be taken to assure that chickens from each dilution remain separated. To be a valid test, at least 75 percent of the uninoculated eggs shall hatch.

(iii) On the third day after normal hatching time, count all unhatched eggs and all dead, paralyzed and ataxic chickens as positive evidence of viral infection.

(iv) A satisfactory titration shall have at least one dilution with between 50 and 100 percent positives and at least one dilution with between 50 and 0 percent positives.

(v) Calculate the EID_{50} by the Spearman-Karber or Reed-Muench method.

(3) At least 21 days post-vaccination, the vaccinates and the controls shall be challenged intracerebrally with a virulent avian encephalomyelitis virus and observed each day for 21 days.

(4) If at least 80 percent of the controls do not show signs of avian encephalomyelitis or die, the test is inconclusive and may be repeated. If at least 19 of 20, or 27 of 30, or 36 of 40 of the vaccinates in each group do not remain free from clinical signs of avian encephalomyelitis during the observation period, the Master Seed Virus is unsatisfactory.

(5) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only one method of administration recommended on the label need be used in the retest. The vaccinates and the controls shall meet the criteria prescribed in paragraph (c)(4) of this section.

(6) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) After a lot of Master Seed Virus has been established as prescribed in paragraphs (a), (b), and (c) of this section, each serial and subserial shall meet the applicable requirements in § 113.135 and the requirements prescribed in this paragraph.

(1) Final container samples from each serial shall be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except that, if the test is inconclusive because of a vaccine virus override, the chicken inoculation test prescribed in § 113.36 may be conducted and the vaccine judged accordingly.

(2) *Safety test.* Final container samples of completed product shall be tested for safety as follows:

(i) At least 25 AE susceptible birds (6 to 10 weeks of age) shall be vaccinated with the equivalent of 10 doses by each of all routes recommended on the label and be observed each day for 21 days.

(ii) If unfavorable reactions attributable to the biological product occur during the observation period, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the product, the test shall be declared inconclusive and repeated, except that, if the test is not repeated, the serial shall be unsatisfactory.

(3) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in such immunogenicity test but not less than $10^{2.5}$ EID_{50} per dose.

[39 FR 44723, Dec. 27, 1974, as amended at 40 FR 18405, Apr. 28, 1975; 40 FR 41089, Sept. 5, 1975; 42 FR 43617, Aug. 30, 1977; 48 FR 33473, July 22, 1983]

§ 113.161 Avian Pox Vaccine.

Fowl Pox Vaccine and Pigeon Pox Vaccine shall be prepared from virus-bearing cell culture fluids or embryonated chicken eggs. Only Master Seed

Virus which has been established as pure, safe, and immunogenic in accordance with the requirements in paragraphs (a), (b), and (c) of this section shall be used for preparing the production seed virus for vaccine production. All serials shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.135 except paragraph (c) of this section and shall meet the requirements prescribed in this section.

(b) Each lot of Master Seed Virus shall be tested for pathogens by the chicken inoculation test prescribed in § 113.36.

(c) Each lot of Master Seed Virus shall be tested for immunogenicity and the selected virus dose to be used shall be established as follows:

(1) Fowl pox susceptible birds all of the same age and from the same source, shall be used as test birds. Twenty or more birds shall be used as vaccinates for each method of administration recommended on the label. Ten additional birds of the same age and from the same source as the vaccinates shall be held as unvaccinated controls.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. Each vaccinate shall receive a predetermined quantity of vaccine virus. Five replicate virus titrations shall be conducted on an aliquot of the vaccine virus to confirm the amount of virus administered to each bird used in the test. At least three appropriate (not to exceed tenfold) dilutions shall be used and the test conducted as follows:

(i) For each dilution, inoculate at least five embryos, 9 to 11 days old, on the chorioallantoic membrane with at least 0.2 ml each. Disregard all deaths during the first 24 hours post-inoculation. To be a valid test, at least four embryos in each dilution shall remain viable beyond 24 hours.

(ii) Examine the surviving embryos for evidence of infection 5 to 7 days post-inoculation.

(iii) A satisfactory titration shall have at least one dilution with between 50 and 100 percent positives and at least one dilution with between 50 and 0 percent positives.

(iv) Calculate the EID$_{50}$ by the Spearman-Karber or Reed-Muench method.

(3) Fourteen to twenty-one days post-vaccination, all vaccinates and controls shall be challenged by the wing web method and observed each day for 10 days. If the wing web method was used for vaccination, the opposite wing shall be used for challenge. Challenge virus shall be provided or approved by Veterinary Services.

(4) If at least 90 percent of the controls do not develop fowl pox during the observation period, the test is inconclusive and may be repeated. If at least 19 of 20, or 27 of 30, or 36 of 40 of the vaccinates in each group do not remain free from clinical signs of fowl pox during the observation period, the Master Seed Virus is unsatisfactory.

(5) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only one method of administration recommended on the label need be used in the retest. The vaccinates and the controls shall meet the criteria prescribed in paragraph (c)(4) of this section.

(6) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) After a lot of Master Seed Virus has been established as prescribed in paragraphs (a), (b), and (c) of this section, each serial and subserial shall meet the requirements in § 113.36, in § 113.135 except paragraph (c), and in this paragraph.

(1) *Safety test.* Final container samples of completed product from each serial shall be tested. Vaccines recommended for use in birds 10 days of age or younger shall be tested in accordance with paragraphs (d)(1) (i), (ii), and (iii) of this section.

(i) Each of 25 susceptible birds 5 days of age or younger, properly identified and obtained from the same source and hatch, shall be vaccinated with the equivalent of 10 doses of vaccine by each of all routes recommended on the label and observed each day for 14 days. Severe clinical signs or death shall be counted as failures. Two-stage sequential testing may be conducted if the first test (which then becomes stage one) has three failures.

(ii) The results shall be evaluated according to the following table:

CUMULATIVE TOTALS

Stage	Number of birds	Failures for satisfactory serials	Failures for unsatisfactory serials
1	25	2 or less	4 or more.
2	50	5 or less	6 or more.

(iii) If unfavorable reactions occur which are not attributable to the product, the test shall be declared inconclusive and may be repeated or, in lieu thereof, the serial declared unsatisfactory.

(iv) Vaccines not recommended for use in birds 10 days of age or younger shall be tested for safety as follows: Each of twenty-five 3- to 5-week-old, fowl-pox susceptible birds shall be vaccinated with the equivalent of 10 doses of vaccine by each of all routes recommended on the label and observed each day for 14 days. If any of the birds show severe clinical signs of disease or death during the observation period due to causes attributable to the product, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the product, the test shall be declared inconclusive and may be repeated or, in lieu thereof, the serial declared unsatisfactory.

(2) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in such immunogenicity test but not less than $10^{2.0}$ EID_{50} per dose.

[39 FR 44724, Dec. 27, 1974, as amended at 40 FR 18406, Apr. 28, 1975; 40 FR 41089, Sept. 5, 1975; 44 FR 33051, June 8, 1979; 48 FR 33473, July 22, 1983]

§ 113.162 Bronchitis Vaccine.

Bronchitis Vaccine shall be prepared from virus-bearing cell culture fluids or embryonated chicken eggs. Only Master Seed Virus which has been established as pure, safe, and immunogenic in accordance with the requirements in paragraphs (a), (b), and (c) of this section shall be used for preparing the production seed virus for vaccine production. All serials shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.135 and the requirements prescribed in this section.

(b) Each lot of Master Seed Virus shall be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except that, if the test is inconclusive because of a vaccine virus override, the test may be repeated and if the repeat test is inconclusive for the same reason, the chicken inoculation test prescribed in § 113.36 may be conducted and the virus judged accordingly.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity and the selected virus dose to be used shall be established as follows:

(1) Bronchitis susceptible chickens, all of the same age and from the same source, shall be used in the virus-recovery test. For each method of administration recommended on the label for each serotype against which protection is claimed, twenty or more chickens shall be used as vaccinates. Ten additional chickens for each serotype against which protection is claimed shall be held as unvaccinated controls.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity tests are conducted. Each vaccinate shall receive a predetermined quantity of vaccine virus. Five replicate virus titrations shall be conducted on an alliquot of the vaccine

virus to confirm the amount of virus administered to each chicken used in such tests. At least three approved (not to exceed tenfold) dilutions shall be used and the test conducted as follows;

(i) For each dilution, inject at least five embyros, 9 to 11 days old, in the allantoic cavity with 0.1 ml each. Deaths occurring during the first 24 hours shall be disregarded, but at least four viable embyros in each dilution shall survive beyond 24 hours of a valid test. After 5 to 8 days incubation, examine the surviving embryos for evidence of infection.

(ii) A satisfactory titration shall have at least one dilution with between 50 and 100 percent positives and at least one dilution with between 50 and 0 percent positives.

(iii) Calculate the EID$_{50}$ by the Spearman-Karber or Reed-Muench method.

(3) Twenty-one to twenty-eight days post-vaccination, all vaccinates and controls shall be challenged by eyedrop with virulent bronchitis virus. A separate set of vaccinates and controls shall be used for each serotype against which protection is claimed. Each challenge virus shall be approved or provided by Veterinary Services and shall titer at least $10^{4.0}$ EID$_{50}$ per ml.

(i) Tracheal swabs shall be taken once, 5 days post-challenge, from each control and vaccinate. Each swab shall be placed in a test tube containing 3 ml of tryptose phosphate broth and antibiotics. The tube and swab shall be swirled thoroughly and if they are to be stored, be immediately frozen and be stored at below −40° C. pending egg evaluation. For each chicken swab, at least five chicken embryos 9 to 11 days old shall be inoculated in the allantoic cavity with 0.2 ml each of broth from each tube.

(ii) All embryos surviving the third day post-inoculation shall be used in the evaluation, except that, if a swab is not represented by at least four embryos, the test of that swab is invalid and the results inconclusive. A tracheal swab shall be positive for virus recovery when any of the embryos in a valid test show typical infectious bronchitis virus lesions, such as but not limited to, stunting, curling, kidney urates, clubbed down, or death during the 4 to 7 day post-inoculation period. If less than 20 percent of the embryos which survive the third day post-inoculation die during the 4 to 7 day post-inoculation period and show no gross lesions typical of infectious bronchitis, they may be disregarded.

(iii) If less than 90 percent of the controls are positive for virus recovery, the test is inconclusive and may be repeated.

(iv) If less than 90 percent of the vaccinates are negative for virus recovery, the Master Seed Virus is unsatisfactory.

(4) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only one method of administration recommended on the label need be used in the retest. The vaccinates and the controls shall meet the criteria prescribed in paragraph (c)(3) of this section.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) After a lot of Master Seed Virus has been established as prescribed in paragraphs (a), (b), and (c) of this section, each serial and subserial shall meet the applicable requirements in § 113.135 and the requirements prescribed in this paragraph, except that, if the vaccine contains more than one virus type, bulk samples taken from each type prior to mixing shall be used in the virus identity tests prescribed in § 113.135(c). The additional requirements in this paragraph shall also be met.

(1) Final container samples from each serial shall be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except that, if the test is inconclusive because of a vaccine virus override, the chicken inoculation test prescribed in § 113.36 may be conducted and the vaccine judged accordingly.

(2) *Safety test.* Final container samples of completed product shall be tested to determine safety for use in bronchitis susceptible young chickens.

(i) Twenty-five susceptible chickens, 5 days of age or younger, properly identified and obtained from the same source and hatch, shall be vaccinated by the eye-drop method with the equivalent of 10 doses of vaccine and observed each day for 21 days post-vaccination. Severe respiratory signs or death shall be counted as failures. Two-stage sequential testing may be conducted if the first test (which then becomes stage one) has three failures.

(ii) The results shall be evaluated according to the following table:

CUMULATIVE TOTALS

Stage	Number of chickens	Failures for satisfactory serials	Failures for unsatisfactory serials
1	25	2	4.
2	50	5	6.

If unfavorable reactions occur which are not attributable to the product, the test shall be declared inconclusive and repeated or, in lieu thereof, the serial declared unsatisfactory.

(3) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the procedure prescribed in paragraph (c)(2) of this section and in this paragraph.

(i) The Newcastle disease virus fraction of combined Newcastle-Bronchitis Vaccines shall be neutralized prior to titration of the bronchitis virus fraction. Equal parts of heat-inactivated Newcastle disease antiserum shall be mixed with each appropriate serial ten-fold dilution of the vaccine. After inactivation, embryos shall be injected with 0.2 ml each and results calculated as a 0.1 ml dose to allow for serum dilution of the vaccine. The allantoic fluids, tested as prescribed in § 113.34 shall not show hemagglutinating activity in the lowest dilution used in the titration.

(ii) Each bronchitis virus type shall be harvested separately and a sample of bulk harvested material shall be collected prior to mixing with the other virus type(s). Each sample shall contain not less than the minimum virus titer stated in the filed Outline of Production.

(iii) To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in such immunogenicity test but not less than $10^{2.0}$ EID_{50} per dose.

[39 FR 44724, Dec. 27, 1974, as amended at 40 FR 18406, Apr. 28, 1975; 40 FR 41089, Sept. 5, 1975; 42 FR 43617, Aug. 30, 1977; 48 FR 33473, July 22, 1983]

§ 113.163 Fowl Laryngotracheitis Vaccine.

Fowl Laryngotracheitis Vaccine shall be prepared from virus-bearing cell culture fluids or embryonated chicken eggs. Only Master Seed Virus which has been established as pure, safe, and immunogenic in accordance with the requirements in paragraphs (a), (b), and (c) of this section shall be used for preparing the production seed virus for vaccine production. All serials shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.135 and the requirements prescribed in this section.

(b) Each lot of Master Seed Virus shall be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except that, if the test is inconclusive because of vaccine virus override, the test may be repeated and if the repeat test is inconclusive for the same reason, the chicken inoculation test prescribed in § 113.36 may be conducted and the virus judged accordingly. Each lot shall also be tested for safety as follows:

(1) Each of at least ten 3 to 4 week old susceptible chickens obtained from the same source and hatch as those used in the immunogenicity test prescribed in paragraph (c) of this section shall be injected intratracheally with 0.2 ml of the virus as used in the vaccine and the chickens observed each day for 14 days.

(2) If more than 20 percent of the chickens die during the observation period, the virus is unsatisfactory.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity and the selected virus dose to be used shall be established as follows:

(1) Fowl laryngotracheitis susceptible chickens all of the same age and from the same source shall be used. Twenty or more chickens shall be used as vaccinates for each method of administration recommended on the label. Ten additional chickens of the same age and from the same source shall be held as unvaccinated controls.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. Each vaccinate shall receive a predetermined quantity of vaccine virus. Five replicate virus titrations shall be conducted on an aliquot of the vaccine virus to confirm the amount of virus administered to each chicken used in the test. At least three appropriate (not to exceed tenfold) dilutions shall be used for vaccine of chicken embryo origin and the test conducted as follows:

(i) For each dilution, inject at least five embryos, 9 to 11 days old, on the chorioallantoic membrane with 0.2 ml each. Disregard all deaths during the first 24 hours post-injection. To be a valid test, at least four embryos in each dilution shall remain viable beyond 24 hours.

(ii) Examine the surviving embryos for evidence of infection 5 to 8 days post-injection.

(iii) A satisfactory titration shall have at least one dilution with between 50 and 100 percent positives and at least one dilution with between 50 and 0 percent positives.

(iv) Calculate the EID_{50} by the Spearman-Karber or Reed-Muench method.

(3) Tissue culture origin vaccine may be titrated by a tissue culture method approved by Veterinary Services and written into the filed Outline of Productions.

(4) Ten to fourteen days post-vaccination, all vaccinates and controls shall be challenged intratracheally or in the orbital sinus with infectious fowl laryngotracheitis virus and observed each day for 10 days. Challenge virus shall be provided or approved by Veterinary Services.

(5) If at least 80 percent of the controls do not die or show clinical signs of fowl laryngotracheitis during the observation period, the test is inconclusive and may be repeated. If at least 19 of 20, 27 of 30, or 36 of 40 of the vaccinates in each group do not remain free of clinical signs of fowl laryngotracheitis during the observation period, the Master Seed Virus is unsatisfactory.

(6) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only one method of administration recommended on the label need be used in the retest. The vaccinates and the controls shall meet the criteria prescribed in paragraphs (c) (4) and (5) of this section.

(7) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) After a lot of Master Seed Virus has been established as prescribed in paragraphs (a), (b), and (c) of this section, each serial and subserial shall meet the applicable requirements in § 113.135 and the requirements prescribed in this paragraph.

(1) Final container samples from each serial shall be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except that, if the test is inconclusive because of a vaccine virus override, the chicken inoculation test prescribed in § 113.36 may be conducted and the vaccine judged accordingly.

(2) *Safety test.* Final container samples of completed product from each serial of modified live virus vaccine shall be tested for safety as provided in this paragraph. Live virus vaccine not prepared with modified live virus shall be tested for safety as provided in the filed Outline of Production.

(i) Twenty-five 3 to 4 week old laryngotracheitis susceptible chickens shall be injected intratracheally with 0.2 ml of vaccine rehydrated at the rate of 30 mls for 1,000 doses. Chickens shall be observed each day for 14 days. Deaths shall be counted as failures. Two-stage sequential testing may be conducted if the first test (which then becomes stage one) has five, six, or seven failures.

(ii) The results shall be evaluated according to the following table:

CUMULATIVE TOTALS

Stage	Number of chickens	Failures for satisfactory serials	Failures for unsatisfactory serials
1	25	4 or less	8 or more.
2	50	10 or less	11 or more.

(iii) If unfavorable reactions occur which are not attributable to the product, the test shall be declared inconclusive and repeated or in lieu thereof, the serial declared unsatisfactory.

(3) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method provided in paragraphs (c) (2) or (3) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in such immunogenicity test but not less than $10^{2.5}$ EID_{50} per dose for chicken embryo origin vaccine and $10^{2.0}$ EID_{50} or $10^{2.5}$ $TCID_{50}$ per dose for tissue culture origin vaccine.

[39 FR 44726, Dec. 27, 1974, as amended at 40 FR 18407, Apr. 28, 1975; 40 FR 41089, Sept. 5, 1975; 41 FR 44359, Oct. 8, 1976; 42 FR 43617, Aug. 30, 1977; 48 FR 33473, July 22, 1983]

§ 113.164 Newcastle Disease Vaccine.

Newcastle Disease Vaccine shall be prepared from virus-bearing cell culture fluids or embryonated chicken eggs. Only Master Seed Virus which has been established as pure, safe, and immunogenic in accordance with the requirements in paragraphs (a), (b), and (c) of this section shall be used for preparing the production seed virus for vaccine production. All serials shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.135, except § 113.34, and the requirements prescribed in this section.

(b) Each lot of Master Seed Virus shall be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except that, if the test is inconclusive because of a vaccine virus override, the test may be repeated and if the repeat test is inconclusive for the same reason, the chicken inoculation test prescribed in § 113.36 may be conducted and the virus judged accordingly.

(c) Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity and the selected virus dose to be used shall be established as follows:

(1) Newcastle Disease susceptible chickens, all of the same age and from the same source, shall be used. Twenty or more chickens shall be used as vaccinates for each method of administration recommended on the label. Ten additional chickens of the same age and from the same source shall be held as unvaccinated controls.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. Each vaccinate shall receive a predetermined quantity of vaccine virus. Five replicate virus titrations shall be conducted on an aliquot of the vaccine virus to confirm the amount of virus administered to each chicken used in the test. At least three appropriate (not to exceed tenfold) dilutions shall be used and the test conducted as follows:

(i) For each dilution, inject at least five embryos, 9 to 11 days old, in the allantoic cavity with at least 0.1 ml each. Disregard all deaths during the first 24 hours post-injection. To be a valid test, at least four embryos in each dilution shall remain viable beyond 24 hours.

(ii) Examine the surviving embryos for evidence of infection 5 to 7 days post-injection.

(iii) A satisfactory titration shall have at least one dilution with between 50 and 100 percent positives and at least one dilution with between 50 and 0 percent positives.

(iv) Calculate the EID_{50} by the Spearman-Karber or Reed-Muench method.

(3) Twenty to twenty-eight days postvaccination, all vaccinates and controls shall be challenged intramuscularly with at least $10^{4.0}$ EID_{50} of virus per chicken and observed each day for 14 days. Challenge virus shall be provided or approved by Veterinary Services.

(4) If at least 90 percent of the controls do not develop clinical signs of Newcastle disease during the observation period, the test is inconclusive and may be repeated. If at least 19 of 20, or 27 of 30, or 36 of 40 of the vaccinates in each group do not remain free from clinical signs of Newcastle disease during the observation period, the Master Seed Virus is unsatisfactory.

(5) The Master Seed Virus shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only one method of administration recommended on the label need be used in the retest. The vaccinates and the controls shall meet the criteria prescribed in paragraph (c)(4) of this section.

(6) A strain identity test acceptable to Veterinary Services shall be conducted.

(7) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) After a lot of Master Seed Virus has been established as prescribed in paragraphs (a), (b), and (c) of this section, each serial and subserial shall meet the applicable requirements in § 113.135, except § 113.34, and the requirements prescribed in this paragraph.

(1) Final container samples from each serial shall be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except that, if the test is inconclusive because of a vaccine virus override, the chicken inoculation test prescribed in § 113.36 may be conducted and the vaccine judged accordingly.

(2) Safety test: Final container samples of completed product from each serial shall be tested to determine whether the vaccine is safe for use in susceptible young chickens. Vaccines recommended for use in chickens 10 days of age or younger shall be tested in accordance with paragraphs (d)(2)(i), (ii), and (iii) of this section.

(i) Twenty-five susceptible chickens, 5 days of age or younger, properly identified and obtained from the same source and hatch, shall be vaccinated by the eye drop method with the equivalent of 10 doses of vaccine and the chickens observed each day for 21 days. Severe respiratory signs or death shall be counted as failures. Two-stage sequential testing may be conducted if the first test (which then becomes stage one) has 3 failures.

(ii) The results shall be evaluated according to the following table:

CUMULATIVE TOTALS

Stage	Number of chickens	Failures for satisfactory serials	Failures for unsatisfactory serials
1	25	2 or less	4 or more.
2	50	5 or less	6 or more.

(iii) If unfavorable reactions occur which are not attributable to the product, the test shall be declared inconclusive and may be repeated.

(iv) Vaccines not recommended for use in chickens 10 days of age or younger shall be tested for safety as follows:

Each of twenty-five 3 to 5 week old Newcastle disease susceptible chickens shall be vaccinated as recommended on the label with the equivalent of ten doses and observed each day for 21 days. If any of the birds show severe clinical signs of disease or death during the observation period due to causes attributable to the product, the serial is unsatisfactory.

(3) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer per dose sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that when tested at any time within the expira-

tion period, each serial and subserial shall have a virus titer of $10^{0.7}$ greater than that used in the immunogenicity test but not less than $10^{3.5}$ EID_{50} per dose.

[39 FR 44727, Dec. 27, 1974, as amended at 40 FR 18407, Apr. 28, 1975; 40 FR 23721, June 2, 1975; 40 FR 41090, Sept. 5, 1975; 42 FR 43618, Aug. 30, 1977; 48 FR 33473, July 22, 1983]

§ 113.165 Marek's Disease Vaccines.

Marek's Disease Vaccine shall be prepared from virus-bearing tissue culture cells. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.135, except paragraph (c), and the requirements prescribed in this section. Each lot of Master Seed Virus shall also be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except lesions typical of turkey herpes virus may be disregarded.

(b) Safety test: The Master Seed Virus shall be nonpathogenic for chickens as determined by the following procedure:

(1) Three groups of at least 50 chickens each at one day of age shall be used. These chickens shall be of the same source and hatch; be susceptible to Marek's disease; and be kept isolated in groups.

(i) *Group 1.* Each chicken shall be injected with 10 times as much viable virus as will be contained in one dose of vaccine, by the route recommended for vaccination.

(ii) *Group 2.* Each chicken shall be injected with a virulent Marek's disease herpes virus at a dosage level that will cause gross lesions of Marek's disease in at least 60% of the chickens within 50 days.

(iii) *Group 3.* Controls.

(2) At least 40 chickens in each group shall survive for 4 days post-injection. All chickens that die shall be necropsied and examined for lesions of Marek's disease and cause of death. The test shall be judged according to the following:

(i) At 50 days of age, the remaining chickens in Group 2 shall be killed and examined for gross Marek's disease lesions. If at least 60 percent of this group do not develop Marek's disease, the test is inconclusive and may be repeated.

(ii) At 120 days of age, the remaining chickens in Groups 1 and 3 shall be weighed, killed, and necropsied. If at least 30 chickens in each of these 2 groups have not survived the 120 day period; or if any of the chickens in Groups 1 and 3 have gross lesions of Marek's disease at necropsy; or if the average body weight of the chickens in Group 1 is significantly (statistically) different from the average in Group 3 at the end of the 120 days, the lot of Master Seed Virus is unsatisfactory.

(c) [Reserved]

(d) Test requirements for release: Except for the virus identity tests in § 113.135(c), each serial and subserial shall meet the applicable requirements prescribed in § 113.135. Final container samples of completed product shall also meet the requirements in paragraphs (d) (1), (2), and (3) of this section. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Purity test.* The chicken embryo inoculation test prescribed in § 113.37 shall be conducted except lesions typical of turkey herpes virus may be disregarded.

(2) *Safety test.* At least 25 one-day old chickens shall be injected, by the route recommended on the label for vaccination, with the equivalent of 10 chicken doses of virus (vaccine concentrated 10X). The chickens shall be observed each day for 21 days. Chickens dying during the period shall be examined, cause of death determined, and the results recorded.

(i) If at least 20 chickens do not survive the observation period, the test is inconclusive.

(ii) If lesions of any disease or cause of death are directly attributable to the vaccine, the serial is unsatisfactory.

(iii) If less than 20 chicks survive the observation period and there are no deaths or lesions attributable to the vaccine, the test may be repeated one time: *Provided*, That, if the test is not repeated, the serial shall be declared unsatisfactory.

(3) *Potency test.* The samples shall be titrated in a cell culture system or by any other titration method acceptable to Veterinary Services. Vaccine samples of desiccated vaccine shall be incubated at 37° C. for 3 days before preparation for use in the titration test required to be performed prior to the release of a product. A satisfactory serial or subserial shall contain at least 1,500 plaque forming units per dose at release and maintain at least 1,000 plaque forming units when tested without incubation at any time before the expiration date.

[39 FR 44728, Dec. 27, 1974, as amended at 40 FR 18408, Apr. 28, 1975; 43 FR 25078, June 9, 1978]

§ 113.166 Bursal Disease Vaccine.

Bursal Disease Vaccine shall be prepared from virus-bearing cell culture fluids or embryonated chicken eggs. Only Master Seed Virus which has been established as pure, safe, and immunogenic in accordance with the requirements in paragraphs (a), (b), and (c) of this section shall be used for preparing the production seed virus for vaccine production. All serials shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.135 and the requirements prescribed in this section.

(b) Each lot of Master Seed Virus shall be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except that, if the test is inconclusive because of a vaccine virus override, the chicken inoculation test prescribed in § 113.36 may be conducted and the virus judged accordingly. Each lot of Master Seed Virus used in the preparation of modified live virus vaccines shall also be nonpathogenic to chickens as determined by the following procedures:

(1) Each of twenty-five 1-day-old bursal disease susceptible chickens (vaccinates) shall be injected subcutaneously with 10 times the recommended dose of vaccine virus and observed for 21 days. Fifteen chickens of the same source and hatch shall be kept isolated as controls.

(i) Seventeen days postvaccination, each of five controls shall be administered at least $10^{3.0}$EID$_{50}$ of a virulent bursal disease virus by eye-drop, isolated, and used as positive controls. The remaining controls shall be used as negative controls.

(ii) If the vaccinates do not remain free of clinical signs of bursal disease, the Master Seed Virus is unsatisfactory. If unfavorable reactions which are not attributable to the Master Seed Virus occur in more than two of the vaccinates, the test shall be declared inconclusive and may be repeated.

(iii) Twenty-one days postvaccination, the vaccinates and the controls shall be necropsied and examined for gross lesions of bursal disease. If more than two of the vaccinates have such lesions, the Master Seed Virus is unsatisfactory, except that, if any of the negative controls or less than four of the positive controls have such lesions, the test is inconclusive and may be repeated. For purposes of this test, gross lesions shall include obvious pathological processes and/or obvious reduction in size of the bursa from normal.

(2) Each of thirty-five 3- to 4-week-old bursal disease susceptible chickens (vaccinates) shall be vaccinated with approximately one minimum protective dose of vaccine virus as determined in paragraph (c) of this section. Each of 10 chickens of the same source and hatch shall be administered at least $10^{3.0}$EID$_{50}$ of a virulent bursal disease virus by eye-drop, isolated, and used as positive controls. Also, each of 20 additional chickens of the same source and hatch shall be isolated and held as negative controls.

(i) Three or four days postvaccination, 10 of the vaccinates, the 10 positive controls, and 10 of the negative controls shall be necropsied and examined for gross lesions of bursal disease. If any of the vaccinates have such lesions, the Master Seed Virus is unsatisfactory, except that, if any of the negative controls or less than 8 of the positive controls have such lesions, the test is inconclusive and may be repeated. For purposes of this test, gross lesions shall include peri-bursal edema and/or edema and/or macroscopic hemorrhage in the bursal tissue.

(ii) Fourteen days post-vaccination, the remaining vaccinates and negative controls shall be necropsied and examined for obvious bursal atrophy. If any of the vaccinates have such atrophy, the Master Seed Virus is unsatisfactory, except that, if any of the negative controls have such atrophy, the test is inconclusive and may be repeated.

(c) Each lot of Master Seed Virus shall be tested for immunogenicity and the selected virus dose to be used shall be established as follows:

(1) Bursal Disease susceptible chickens, all of the same age (3 weeks or younger) and from the same source, shall be used. Twenty or more chickens shall be used as vaccinates for each method of administration recommended on the label. Ten additional chickens of the same age and from the same source shall be held as unvaccinated controls.

(2) A geometric mean titer of the vaccine produced from the highest passage of the Master Seed Virus shall be established before the immunogenicity test is conducted. Each vaccinate shall receive a predetermined quantity of vaccine virus. Five replicate virus titrations shall be conducted on an aliquot of the vaccine virus to confirm the amount of virus administered to each chicken used in the test. At least three appropriate (not to exceed tenfold) dilutions shall be used to conduct the titrations by a method acceptable to Veterinary Services.

(3) When the test chickens are 28 to 35 days of age but not less than 14 days postvaccination, each vaccinate and each control shall be challenged by eye-drop with a virulent bursal disease virus provided or approved by Veterinary Services.

(i) Three to five days postchallenge, all vaccinates and controls shall be necropsied and examined for gross lesions of bursal disease as described in paragraph (b)(2)(i) of this section.

(ii) If at least 19 of 20, or 27 of 30, or 36 of 40 vaccinates in each group are not free from such lesions, the Master Seed Virus is unsatisfactory, except that, if less than 90 percent of the controls have such lesions, the test is inconclusive and may be repeated.

(4) The Master Seed Virus shall be retested for immunogenicity in 3 years from the original testing unless use of the lot previously tested is discontinued. Only one method of administration recommended on the label need be used in the retest. The vaccinates and the controls shall meet the criteria prescribed in paragraph (c)(3) of this section.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed Virus shall be granted by Veterinary Services.

(d) After a lot of Master Seed Virus has been established as prescribed in paragraphs (a), (b), and (c) of this section, each serial and subserial shall meet the applicable requirements in § 113.135 and the requirements prescribed in this paragraph.

(1) *Tests for pathogens.* Final container samples from each serial shall be tested for pathogens by the chicken embryo inoculation test prescribed in § 113.37, except that, if the test is inconclusive because of a vaccine virus override, the chicken inoculation test prescribed in § 113.36 may be conducted and the serial judged accordingly.

(2) *Safety tests.* (i) Final container samples of completed product from each serial shall be tested to determine whether the vaccine is safe as follows:

(A) For vaccines intended for parenteral administration, each of twenty-five 1-day-old bursal disease susceptible chickens shall be vaccinated with the equivalent of 10 doses by subcutaneous injection.

(B) For vaccines intended for drinking water administration, each of twenty-five 4- to 5-week-old bursal disease susceptible chickens shall be vaccinated orally with the equivalent of 10 doses.

(C) Ten chickens of the same source and hatch shall be maintained in isolation as negative controls. The vaccinates and controls shall be observed each day for 21 days.

(ii) If unfavorable reactions which are attributable to the biological product occur during the observation period, the serial is unsatisfactory. If unfavorable reactions occur in more than one of the controls or if unfavorable reactions which are not attributable to the biological product occur in more than two of the vaccinates, the test shall be declared inconclusive and repeated, except that, if the test is not repeated, the serial shall be unsatisfactory.

(3) *Virus titer requirements.* Final container samples of completed product shall be tested for virus titer using the titration method used in paragraph (c)(2) of this section. To be eligible for release, each serial and each subserial shall have a virus titer sufficiently greater than the titer of vaccine virus used in the immunogenicity test prescibed in paragraph (c) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a virus titer of log $10^{0.7}$ greater than that used in such immunogenicity test, but not less than log $10^{2.0}$ titration units (PFU or ID_{50}'s) per dose.

[44 FR 60263, Oct. 19, 1979, as amended at 44 FR 67087, Nov. 23, 1979; 48 FR 33473, July 22, 1983]

§ 113.167 Tenosynovitis Vaccine.

Tenosynovitis Vaccine shall be prepared from virus-bearing cell culture fluids or embryonated chicken eggs.

Only Master Seed which has been established as pure, safe, and immunogenic shall be used for preparing seeds for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.135, except (a)(3)(ii) and (c), and the special requirements in this section.

(b) Each lot of Master Seed shall be tested for:

(1) Pathogens by the chicken inoculation test prescribed in § 113.36.

(2) Lymphoid leukosis virus contamination as follows:

(i) Each of at least 10 3-week-old or older lymphoid leukosis free chickens from the same source and hatch shall be injected intra-muscularly with an amount of Master Seed equal to 100 label doses of vaccine. At least 15 chickens of the same source and hatch shall be used as controls; 5 or more shall be unvaccinated and serve as negative controls; 5 or more shall be injected with subgroup A lymphoid leukosis virus; and 5 or more with subgroup B lymphoid leukosis virus. Each group of control chickens shall be held isolated from each other and from the vaccinates.

(ii) Twenty-one to 28 days postinoculation, blood samples shall be taken from each chicken and the serum separated using a technique conducive to virus preservation. These serums shall be used as inocula in the complement fixation for avian lymphoid leukosis (COFAL) test prescribed in § 113.31.

(iii) Serums from the vaccinates shall be tested separately, but serums within each control group may be pooled. A valid test shall have positive COFAL reactions from each virus inoculated group and negative reactions from the uninoculated controls. If any of the chickens injected with the Master Seed have positive COFAL test reactions in a valid test, the Master Seed is unsatisfactory.

(3) Identity using the following agar gel immunodiffusion test. The undiluted Master Seed may be used as test antigen or the Master Seed may be inoculated onto the chorio-allantoic membrane (CAM) of fully susceptible chicken embryos and the infected CAMs ground and used as antigen. A known tenosynovitis antiserum and a known tenosynovitis antigen shall be used in the test. A precipitin line shall form between the test antigen and the known antiserum in the center well which shows identity with the line formed between the antiserum and the known antigen, or the Master Seed is unsatisfactory.

(4) Safety using the following chicken test:

(i) For vaccines intended for use in chickens less than 14 days of age, Master Seed equal to 10 label doses shall be administered subcutaneously to each of 25 1-day-old tenosynovitis susceptible chickens.

(ii) For vaccines intended for use only in chickens 14 days of age or older, Master Seed equal to 10 label doses shall be administered subcutaneously to each of 25 4-week-old or older tenosynovitis susceptible chickens.

(iii) The vaccinates shall be observed each day for 21 days. If unfavorable reactions occur which are attributable to the vaccine, the Master Seed is unsatisfactory. If unfavorable reactions occur which are not attributable to the vaccine, the test is inconclusive and may be repeated.

(c) Each lot of Master Seed shall be tested for immunogenicity. The selected virus dose shall be established as follows:

(1) Tenosynovitis susceptible chickens, of the same age and from the same source shall be used as test birds. Vaccines intended for use in very young chickens shall be administered to chickens of the youngest age for which the vaccine is recommended. Vaccines intended for use in older chickens shall be administered to 4-week-old or older chickens. Twenty or more vaccinates shall be used for each method of administration recommended on the label. Ten or more chickens shall be held as unvaccinated controls.

(2) A geometric mean titer of the vaccine produced at the highest passage from the Master Seed shall be established using a method acceptable to Veterinary Services before the immunogenicity test is conducted. A predetermined quantity of vaccine virus shall be administered to each vaccinate. Five replicate virus titrations shall be conducted on an aliquot of the vaccine virus to confirm the dose.

(3) Twenty-one to 28 days postvaccination, each vaccinate and control shall be challenged by injecting virulent virus furnished or approved by Veterinary Services into one foot pad. The vaccinates and controls shall be observed each day for 14 days. If at least 90 percent of the controls do not develop swelling and discoloration in the phalangeal joint area of the injected foot pad typical of infection with tenosynovitis virus, the test is inconclusive and may be repeated. If at least 19 of 20, 27 of 30, or 36 of 40 vaccinates do not remain free from these signs, disregarding transient swelling which subsides within 5 days postchallenge, the Master Seed is unsatisfactory.

(4) The Master Seed shall be retested for immunogenicity in 3 years unless use of the lot is discontinued. Only one method of administration recommended on the label need be used in the retest. The vaccinates and controls shall meet the criteria prescribed in paragraph (c)(3) of this section.

(5) An Outline of Production change shall be made before authority for use of a new lot of Master Seed shall be granted by Veterinary Services.

(d) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in § 113.135, except (c), and the requirements in this paragraph.

(1) *Purity.* Final container samples of completed product from each serial shall be tested for pathogens by the chicken inoculation test prescribed in § 113.36.

(2) *Safety.*

(i) Final container samples of completed product from each serial shall be safety tested as follows:

(A) For vaccines intended for use in very young chickens, each of 25 1-day-old tenosynovitis susceptible chickens shall be vaccinated with the equivalent of 10 doses by one method recommended on the label.

(B) For vaccines intended for use in older chickens, each of 25 4-week-old or older tenosynovitis susceptible chickens shall be vaccinated with the equivalent of 10 doses by one method recommended on the label.

(ii) The vaccinates shall be observed each day for 21 days. If unfavorable reactions occur which are attributable to the product, the serial is unsatisfactory. If unfavorable reactions occur in more than two vaccinates which are not attributable to the product, the test is inconclusive and may be repeated. If the test is not repeated, the serial is unsatisfactory.

(3) *Virus titer requirements.* Final container samples of completed product shall be titrated by the method used in paragraph (c)(2) of this section. To be eligible for release, each serial and subserial shall have a virus titer sufficiently greater than the titer of the vaccine virus used in the immunogenicity test prescribed in paragraph (c) of this section to assure that, when tested at any time within the expiration period, each serial and subserial shall have a virus titer $10^{0.7}$ greater

than that used in the immunogenicity test, but not less than log $10^{2.0}$ titration units (PFU or ID_{50}) per dose.

(4) *Identity.* Bulk or final container samples of completed product from each serial shall be tested for identity as prescribed in paragraph (b)(3) of this section and shall meet the criteria stated therein.

[50 FR 438, Jan. 4, 1985]

DIAGNOSTICS AND REAGENTS

§ 113.200 Tuberculin, Intradermic.

Tuberculin, Intradermic, is a filtrate produced from cultures of Pn, C, and Dt strains of *Mycobacterium tuberculosis* (supplied by Veterinary Services) which has been inactivated and is nontoxic. Each serial shall be tested for purity, safety, potency, and special chemical tests in accordance with the conditions prescribed for each test. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Each serial shall be tested for purity as provided in this paragraph.

(1) Final container samples of completed product shall be tested for viable bacteria and fungi as prescribed in § 113.26.

(2) A 20 ml sample shall be centrifuged and the sediment examined microscopically for the presence of acid-fast (Ziehl-Nielsen stain) or other microorganisms (Gram stain). A serial which contains microorganisms is unsatisfactory for release.

(b) *Safety test.* Final container samples of completed product from each serial shall be tested for safety. Two mature guinea pigs shall be injected subcutaneously with 1 ml and observed for 10 days. If unfavorable reactions attributable to the product occur during the observation period, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the product, the test shall be declared inconclusive and repeated: *Provided,* That if the test is not repeated, the serial shall be declared unsatisfactory.

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be subjected to a comparison test using a Reference Tuberculin supplied by Veterinary Services. Test animals shall be 10 sensitized white female guinea pigs from one source which weigh 500-700 grams at the beginning of the test and which have not been used in a previous test. The comparison test shall be conducted in accordance with the procedures prescribed in paragraphs (c) (1), (2), (3), (4), (5), (6), (7), and (8) of this section.

(1) The guinea pigs shall be sensitized with a sterile heat-killed suspension of equal amounts of strains Pn, C, and Dt of *Mycobacterium tuberculosis.* The heat-killed sensitizing agent shall be injected in a volume of 0.5 ml per guinea pig. The guinea pigs shall be considered sensitized for testing not less than 30 days nor more than 120 days post-injection.

(2) The guinea pigs shall be prepared for sensitivity testing at least 4 hours prior to the injection of tuberculin. The entire abdominal and flank areas shall be clipped, a depilatory agent applied for 5-10 minutes, the area rinsed with warm water, and dried.

(3) Dilutions of 1:100, 1:200, and 1:400 shall be prepared with the Reference Tuberculin and the unknown tuberculin. Three test sites on each side of and equidistant from the abdominal midline shall be chosen on each guinea pig. Using a tuberculin syringe and needle, 0.05 ml of each dilution shall be injected intradermally at one of the test sites which has been randomly selected for the dilution.

(4) The sensitivity of the tuberculins shall be determined 24 hours after injected by measuring the area of erythema. Measurements in millimeters shall be made anterior of the greatest diameter and perpendicular to the first measurement. The square millimeter shall be calculated by multiplying the two measurements.

(5) The total area of response for each tuberculin tested shall be determined by adding the areas of erythema for each dilution of each of the test animals in a group. The sums of the areas of erythema for all three dilutions of each tuberculin shall be added to give the total area of tuberculin response.

(6) The total tuberculin response area of the serial being tested shall be

expressed as a percentage of the total tuberculin response area of the Reference Tuberculin. (The total response area of the serial divided by the total response area of the Reference Tuberculin times 100.)

(7) If the total tuberculin response area of the serial being tested does not fall between 75 percent and 125 percent of the total tuberculin response area of the Reference Tuberculin, the serial is unsatisfactory.

(8) Two unsensitized guinea pigs are given 0.05 ml intradermal injections of 1:4 and 1:10 dilutions of both the serial being tested and the Reference Tuberculin as a control for nonspecific positive reactions. If positive reactions are observed with the Reference Tuberculin, the test is considered a "No Test" and repeated. If positive reactions are observed with the serial being tested only, the serial is unsatisfactory.

(d) *Special chemical tests and requirements.* Final container samples of completed product from each serial shall be tested as follows:

(1) *Hydrogen ion concentration.* The hydrogen ion concentration shall be determined with a pH meter which has been standardized with a pH 7.0 buffer just prior to use. The pH of the product shall be 7.0±0.3.

(2) *Total nitrogen determination.* The nitrogen content shall be determined by the Kjeldahl method on duplicate 15 ml samples consisting of 5 ml from each of three vials. The total nitrogen content of the product shall be 0.18 percent±0.06 percent.

(3) *Trichloroacetic acid precipitable nitrogen.* The determination of precipitable nitrogen by a final concentration of 4 percent trichloroacetic acid shall be made by the Kjeldahl method on duplicate 15 ml samples, consisting of 5 ml from each of three vials. The trichloroacetic acid precipitable nitrogen content shall be 0.047 percent±0.01 percent.

(4) *Phenol determination.* The phenol content shall be determined by direct titration with a standardized bromide-bromate solution. (A correction factor of 0.04 should be subtracted from the final value in the determination of phenol in tuberculin.) The phenol content shall be 0.54 percent±0.04 percent.

(5) *Clarity.* The product shall be optically clear and free from any extraneous particles.

[39 FR 16857, May 10, 1974. Redesignated at 39 FR 25463, July 11, 1974]

§ 113.201 Pullorum antigen.

Pullorum Antigen shall be produced from a culture of representative strains of *Salmonella pullorum* which are of known antigenic composition, high agglutinability, but are not sensitive to negative and nonspecific serum. Each serial shall be tested for purity, density, preservative content, sensitivity, homogeneity, and hydrogen ion concentration. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product shall be tested for viable bacteria and fungi as prescribed in § 113.26. In addition, each serial shall be free from extraneous organisms as determined by Gram staining and microscopic examination.

(b) *Nephelometric determination of bacterial density.* The bacterial density shall be 80±15 times McFarland No. 1 standard for stained antigen K's and 50±10 times McFarland No. 1 standard for tube antigen.

(c) *Preservative requirements.* (1) The formalin content of Pullorum Stained Antigen K shall be 1.0±0.2 percent as determined by a colorimetric method.

(2) The phenol content for Pullorum Tube Antigen shall be 0.55±0.05 percent as determined by direct titration with a standardized bromide-bromate solution.

(d) *Sensitivity requirements.* (1) Each serial of antigen shall be compared with a reference antigen of known sensitivity using positive and negative chicken serum. The manufacturers' recommendations for use on the accompanying label or package insert shall be followed. The recommended time limit specified for each antigen shall be carefully observed in the test.

(2) A total of at least 12 serums shall be used. This shall include at least three definitely positive, at least three weakly positive, and at least six negative serums. At least three positive

chicken serums diluted with negative chicken serum shall be used to further assay comparative sensitivity between test and reference plate antigens. All test antigens shall agree closely with the reference antigen. Tests in which variation of readings between the reference and test antigen would result in a different National Poultry Improvement Plan classification shall be regarded as unsatisfactory. No unsatisfactory tests among the six or more negative serums and not more than one unsatisfactory test among the six or more positive serums shall be permitted. All tests performed shall be included for evaluation of the sensitivity assay. In the event of an unsatisfactory test using positive serums, at least three additional definitely positive and three additional weakly positive serums shall be tested. If not more than one unsatisfactory test is obtained with the additional serums, the antigen shall be acceptable.

(e) *Homogeneity requirement.* Antigens shall show no evidence of autoagglutination or unusual appearance such as the presence of flakes, specks, or a preponderance of filament forms. Microscopic examination shall be made in this determination.

(f) *Hydrogen ion concentration.* The hydrogen ion concentration shall be determined with a pH meter which has been standardized with a pH 4.0 buffer just prior to use. The pH of Pullorum Stained Antigen K shall be 4.6±0.4. No pH level is specified for Pullorum Tube Antigen but after dilution as recommended for use, it shall have a pH of 8.2 to 8.5.

[39 FR 16857, May 10, 1974. Redesignated at 39 FR 25463, July 11, 1974, and amended at 40 FR 760, Jan. 3, 1975]

§ 113.202 Avian mycoplasma antigen.

Mycoplasma antigens shall be prepared from organisms, grown in broth cultures, that are inactivated and standardized. Plate antigens shall be stained with a dye acceptable to Veterinary Services (VS). Final container samples of completed product from each serial shall be tested for density, preservative content, homogeneity, hydrogen ion concentration, purity, sensitivity, and specificity in accordance with the conditions prescribed for each test. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Density requirements.* A 2.5 ml sample of completed antigen shall be diluted with 2.5 ml of buffer solution formulated in the same manner as the vehicle of the antigen being tested in a modified Hopkins tube and then sedimented at 1,000 x g in a refrigerated centrifuge at 20° C for 90 minutes. If the packed cell volume of the completed antigen is not 1.2 percent (±0.4 percent), the serial is unsatisfactory.

(b) *Preservative requirements.* Preservatives shall be as specified in the Outline of Production filed with VS in accordance with 9 CFR 114.8. If phenol is used, a direct titration with a standardized bromide-bromate solution shall be made. If the final concentration of phenol is not 0.25 percent (±0.05 percent), the serial is unsatisfactory.

(c) *Homogeneity requirements.* (1) Plate antigen shall be checked on a plate for homogeneity and autoagglutination. If plate antigen is not homogeneous and free of large visible particles (strands or clumps) or if it autoagglutinates, the serial is unsatisfactory.

(2) Stereo-microscopic examination shall be used when necessary to evaluate a granular appearing antigen.

(d) *Hydrogen ion concentration.* The hydrogen ion concentration shall be determined with a pH meter which has been standardized with a pH buffer just prior to use. The pH of Mycoplasma Gallisepticum Antigen shall be 6.0±0.2. The pH of Mycoplasma Synoviae Antigen and Mycoplasma Meleagridis Antigen shall be 7.0±0.2.

(e) *Purity requirements.* The antigen shall be tested for viable bacteria and fungi as prescribed in § 113.26.

(f) *Sensitivity requirements.* The reactivity of each antigen shall be tested by comparing the agglutination reactions of each serial of antigen with the agglutination reactions of a standard reference antigen which is supplied by or acceptable to VS. A set consisting of five known positive and five known negative serums shall be used. The negative serums shall be tested against the antigens undiluted and the positive serums shall be tested against the antigens diluted 1:4 in buffer solution formulated in the same manner as the vehicle of the antigen being tested. If negative serums do not have negative reactions in this test, the serial is unsatisfactory. If the test antigen and the reference antigen do not have the same agglutination reactions with at least four of the five positive serums used, the serial is unsatisfactory.

(1) The sensitivity of Mycoplasma Gallisepticum Antigen shall be tested using a set of chicken and a set of turkey serums (the positive serums shall have varying degrees of reactivity from weakly positive to strongly positive).

(2) The sensitivity of Mycoplasma Synoviae Antigen shall be tested using chicken serums.

(3) The sensitivity of Mycoplasma Meleagridis Antigen shall be tested using turkey serums.

(g) *Specificity requirements.* Mycoplasma Synoviae Antigen shall be examined for cross-agglutination with five *Mycoplasma gallisepticum* antiserums (chicken origin); Mycoplasma Meleagridis Antigen shall be examined for cross-agglutination with five *Mycoplasma gallisepticum* antiserums (turkey origin) and five *Mycoplasma synoviae* antiserums (turkey origin). Tests shall be conducted with undiluted antigen. If cross-agglutination occurs, the serial is unsatisfactory.

[48 FR 33474, July 22, 1983]

§ 113.203 Tuberculin—PPD Bovis, Intradermic.

Tuberculin—PPD Bovis, Intradermic is a purified protein derivative produced from cultures of *Mycobacterium bovis* Strain AN-5 (supplied by Veterinary Services), which has been inactivated and is nontoxic. Each serial shall be tested for purity, safety, potency, and special chemical characteristics in accordance with the conditions prescribed for each test. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Each serial shall be tested for viable bacteria and fungi as prescribed in § 113.26.

(b) *Safety test.* Final container samples of completed product from each serial shall be tested for safety as prescribed in § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be subjected to a comparison specificity test using a Reference PPD Tuberculin supplied by Veterinary Services.

(1) *Test animals.* White female guinea pigs from one source, which weigh 500 to 700 grams at the beginning of the test, and which have not been used in a previous test, shall be used in the specificity test. Twenty-three guinea pigs (10 sensitized with *M. bovis*, 10 sensitized with *M. avium* and three unsensitized) shall be required for each serial being tested, and 20 guinea pigs (10 sensitized with *M. bovis* and 10 sensitized with *M. avium*) shall be required for the Reference PPD Tuberculin. Allowance should be made for deaths during the sensitization period.

(2) *Sensitization of guinea pigs.*

(i) Sensitize one group of guinea pigs to *M. bovis.* Inject each animal intramuscularly with 0.5 ml of a sterile heat-killed suspension of *M. bovis* Strain AN-5 supplied by Veterinary Services.

(ii) Sensitize one group of guinea pigs to *M. avium.* Inject each animal intramuscularly with 0.5 ml of a sterile heat-killed suspension of *M. avium* Strain D-4 supplied by Veterinary Services.

(iii) Maintain an unsensitized group as control animals.

(3) Thirty-five days post-injection, the guinea pigs shall be used for tuberculin testing.

(4) The sensitized animals and controls shall be prepared at least 4 hours prior to injection of PPD tuberculin by clipping the hair from the entire abdominal and flank areas, applying a depilatory agent for 5 to 10 minutes, then rinsing with warm water and drying.

(i) Select four sites on each guinea pig for injection of PPD tuberculin. Two sites shall be on each side of the midline and spaced a sufficient distance from each other to avoid overlapping of skin reactions.

(ii) Prepare four dilutions of the Reference PPD Tuberculin and each serial of PPD tuberculin being tested so as to contain 0.6, 1.2, 2.4, and 4.8 micrograms of protein per 0.1 ml dose.

Each of the four dilutions of the same tuberculin shall be randomly assigned a site on a guinea pig.

(iii) Inject one dose of each dilution at the assigned site using a tuberculin syringe.

(5) *Measurement of skin reactions.* Measure the area of erythema produced at each site on each guinea pig 24 hours following injection of PPD tuberculin. Measurements in millimeters shall be made anterior to posterior across the greatest diameter and perpendicular to the first measurement. Calculate the area of erythema in square millimeters at each site by multiplying the two measurements.

(6) *Calculation of average response per guinea pig.* Obtain the total area of erythema for each guinea pig by adding the areas of the four test sites. Add these composite areas of erythema from all guinea pigs with the same sensitization and the same PPD tuberculin injection, then divide by the number of animals in the group. The number obtained is the average response per guinea pig to the PPD tuberculin for the given type of sensitization.

(7) *Determination of specificity index.* The specificity index of a PPD tuberculin is determined by subtracting the average response obtained on *M. avium* sensitized guinea pigs from the average response obtained on *M. bovis* sensitized guinea pigs.

(8) *Validity of bioassay.* The bioassay test results obtained on serials tested concurrently in a single test series are valid if the specificity index of the reference PPD tuberculin is at least 400 square millimeters. If the results are not valid, the bioassay test series must be repeated with a different set of sensitized guinea pigs.

(9) *Reactions in unsensitized guinea pigs.* If a positive reaction (erythema) is observed in one or more of the 3 unsensitized guinea pigs, the serial is unsatisfactory.

(10) *Interpretation of specificity index.* When a bioassay is valid and reactions are not observed in unsensitized guinea pigs, the following interpretation of the specificity index will be used for classifying each serial of PPD tuberculin:

Specificity index	Classification
440 mm^2 or greater	Satisfactory.
Between 360 mm^2 and 440 mm^2	Inconclusive.
Less than 360 mm^2	Unsatisfactory.

(11) *Second stage test.* If a serial is classified as inconclusive, it can be declared unsatisfactory or undergo a second stage test. The second stage shall be conducted in a manner identical to the first stage, except that unsensitized guinea pig controls are not necessary. The results are evaluated by combining the results obtained on all guinea pigs tested in stages one and two. Calculate the average response on the 20 *M. bovis* sensitized animals and on the 20 *M. avium* sensitized animals and determine the specificity index. An inconclusive serial is satisfactory after the second stage test, if its specificity index is 400 square millimeters or more, and unsatisfactory if its specificity index is less than 400 square millimeters.

(d) *Special chemical tests and requirements.* Final container samples of completed product from each serial shall be tested as follows:

(1) *Protein concentration.* The final product shall contain a protein concentration of 1.0±0.1 mg/ml. The Microkjeldahl Test for Nitrogen shall be used.

(2) *Phenol content.* Phenol content of the final product shall be 0.50 percent plus or minus 0.04 percent. A direct titration with a standardized bromide-bromate solution shall be conducted.

[41 FR 8471, Feb. 27, 1976, as amended at 41 FR 21760, May 28, 1976; 41 FR 32883, Aug. 6, 1976]

BLOOD ORIGIN PRODUCTS

§ 113.250 General requirements for biological products of animal blood origin.

Each serial of biological product prepared from the blood of animals shall comply with the general requirements prescribed in this section unless otherwise provided for in a Standard Requirement or approved Outline of Production for such product. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) Biological products of animal blood origin prepared in the United States shall be obtained from blood of animals maintained at licensed establishments. Such products offered for importation into the United States shall be prepared from the blood of animals maintained at the establishment entered on the permit as having prepared the product.

(b) Only healthy animals shall be used and the fitness shall be determined by physical examination by, or under the supervision of, a veterinarian and by tests for infectious diseases.

(1) No animal shall be used while showing clinical signs of disease. If the body temperature is normal, this restriction shall not apply to an animal having localized lesions, contusions, or slight lameness, but shall apply if the animal is feverish, in pain, or distress.

(2) New animals shall be subjected to applicable tests for the species. Such tests shall be listed in the filed Outline of Production and records maintained of results obtained. No animal shall be used for production of blood which has been found positive when tested for an infectious disease. Retests shall be conducted as deemed necessary by the Deputy Administrator.

(c) Serum and antiserum of equine origin shall be heated at 58.5° C. for 60 minutes, with a tolerance of 0.5° above and below that temperature. Serum and antiserum of bovine and porcine origin shall be heated in like manner for 30 minutes. Neither serum nor antiserum shall contain preservative at the time of heating.

(d) Serum and antiserum heated as provided in paragraph (c) of this section, shall be cooled immediately thereafter to 15° C. or lower, and thus held until properly preserved. It shall be preserved, mixed, and tested by methods described in the licensee's outline.

(e) Licensees shall keep detailed records relative to each batch of antiserum or serum pasteurized and each serial prepared for marketing. Recording thermometer charts shall bear full information concerning the antiserum or serum heated and tests made of the equipment.

(f) *Purity requirements.* Biological products of animal blood origin shall contain only serum constituents, preservatives, and safe amounts of chemicals used in the manufacturing procedures. Final container samples of completed product shall be tested for viable microorganisms as provided in § 113.26.

(g) *Safety requirements.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b).

(h) If no label claim for specific antibody content can be substantiated by the licensee, the product shall be considered a normal serum: *Provided,* That, if the serum does contain demonstrable antibodies which have been produced in response to specific antigens injected into the blood producing animals, the product shall be considered an antiserum, except that:

(1) An antiserum concentrated at least twofold by the removal of water may be considered an antibody concentrate; and

(2) An antiserum fractionated by suitable means to remove most of the non-globulin material and concentrated to increase the amount of globulin at least twofold over the amount in the original antiserum may be considered a globulin concentrate.

(i) Normal serum, antiserum, and antiserum derivatives shall contain at least one preservative in the following table. The amount shall be within the range of concentration set forth.

(1) Phenol 0.25 to 0.55 percent, or

(2) Cresol 0.10 to 0.30 percent, and/or

(3) Thimerosal 0.01 to 0.03 percent, or

(4) Other preservative(s) specified in the approved Outline of Production for the product.

(j) If a potency test has been issued in a Standard Requirement or is written in an approved Outline of Production for an antiserum, an antiserum concentrate, or a globulin concentrate, the potency shall be sufficient for the product to satisfactorily meet the requirements of such test. Unless otherwise specified in the test procedure, the test sample of antiserum concentrate or globulin concentrate shall be diluted with 1 percent peptone solution to a volume equal to the contents of the sample times the concentration factor specified in such approved Outline of Production prior to conducting the test.

(k) If a potency test has not been issued in a Standard Requirement or is not written into an approved Outline of Production for an antiserum, an antiserum concentrate, or a globulin concentrate, such product shall meet the requirements in this paragraph.

(1) The globulin content of antiserum, normal serum, and globulin concentrate shall be determined by electrophoretic mobility or other equally acceptable tests.

(i) The globulin content of antiserum and normal serum shall equal or exceed the amounts per ml listed according to the species of origin as follows:

Species	Globulin (mg/ml)
Bovine	45
Equine	50
Porcine	35
Canine	25
Feline	25

(ii) The globulin content of globulin concentrate shall exceed the value given for the antiserum from a particular species by the multiple of the concentration factor prescribed in the approved Outline of Production.

(iii) Globulin concentrates shall be fractionated in such a manner that the protein content shall contain greater than 90 percent globulin as determined by electrophoretic mobility or other acceptable tests.

(2) The level of protein content for antiserum and normal serum shall equal or exceed the amounts per ml listed according to the species of origin as follows:

Species	Protein (mg/ml)
Bovine	60
Equine	60
Porcine	55
Canine	45
Feline	45

(3) The protein content of an antiserum concentrate shall exceed the value given in the table for the antiserum from a particular species in paragraph (f)(2) of this section by the multiple of the concentration factor prescribed in the approved Outline of Production.

(Approved by the Office of Management and Budget under control number 0579-0013)

[39 FR 16859, May 10, 1974. Redesignated at 39 FR 25463, July 11, 1974, and amended at 40 FR 51414, Nov. 5, 1975; 48 FR 57473, Dec. 30, 1983]

§ 113.251 Tetanus Antitoxin.

Tetanus Antitoxin is a specific antibody obtained from the blood of healthy horses hyperimmunized with an antigen prepared with a toxin-producing strain of *Clostridium tetani*. Each serial shall meet the general requirements provided in paragraph (a) of this section and shall be tested for purity, safety, and potency as provided in paragraphs (b), (c), and (d) of this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) *General requirements.* The amount of antitoxin in a final container shall be the amount which is delivered from such container when opened and inverted until the flow stops. A graduated volumetric cylinder which conforms to the National Bureau of Standards requirements shall be used. The reading shall be made at the bottom of the meniscus. Volumes of 10 ml or less shall be recorded to the nearest 0.1 and volumes over 10 ml shall be recorded to the nearest ml.

(1) All final containers of Tetanus Antitoxin shall yield not less than the labeled unitage of antitoxin throughout the dating period. The minimum package size permitted for marketing in the United States shall be a 1,500 unit vial.

(2) The expiration date of Tetanus Antitoxin shall be not more than 3 years after the date of a potency test which demonstrates that the recoverable antitoxin from the final container provides at least 20 percent excess over the number of units claimed on the label or not more than 1 year after

the date of a potency test which demonstrates that the recoverable antitoxin from the final container provides 10 to 19 percent excess over the number of units claimed on the label.

(b) *Purity test.* Final container samples of completed product from each serial shall be tested for viable bacteria and fungi as prescribed in § 113.26.

(c) *Safety test.* Final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b).

(d) *Potency test.* Bulk or final container samples of completed product from each serial shall be assayed to calculate the units of Tetanus Antitoxin in each final container. A comparative toxin-antitoxin neutralization test shall be conducted using a standard antitoxin and a standard toxin. All dilutions shall be made in M/15 phosphate buffered (pH) 7.4 physiological saline with 0.2 percent gelatin.

(1) One ml of the Standard Antitoxin shall be diluted before use so the final volume contains 0.1 unit per ml. The dilution shall be held at 20° to 25 °C for 30 minutes prior to combination with a test does of toxin.

(2) The Standard Toxin test dose is that amount which when mixed with 0.1 unit of Standard Antitoxin, incubated at 20° to 25 °C for 1 hour, and injected subcutaneously into a 340 to 380 gram guinea pig, results in death of that guinea pig within 60 to 120 hours with clinical signs of tetanus. The toxin shall be diluted so the test dose shall be in 2.0 ml.

(3) A mixture of diluted Standard Toxin and diluted Standard Antitoxin shall be made so that 0.1 unit of antitoxin in 1 ml is combined with a test dose of toxin. This Standard Toxin-Antitoxin mixture shall be held at 20° to 25 °C for 1 hour before injections of guinea pigs are made.

(4) A sample from each serial of antitoxin shall be prepared as was the Standard Toxin-Antitoxin mixture; except the amount of antitoxin shall be based on an estimation of the expected potency. When testing is done on bulk material, the final container fill shall reflect the endpoint value plus 10 percent overage for 1 year dating and 20 percent overage for 3 year dating.

(5) Normal guinea pigs weighing within a range of 340 to 380 grams shall be used. Pregnant guinea pigs must not be used.

(i) Each of two guinea pigs (controls) shall be injected subcutaneously with a 3 ml dose of the Standard Toxin-Antitoxin mixture. Injections shall be made in the same order that toxin is added to the dilutions of antitoxins. These shall be observed parallel with the titration of one or more unknown antitoxins.

(ii) Two guinea pigs shall be used as test animals for each dilution of the unknown antitoxin. A 3.0 ml dose shall be injected subcutaneously into each animal.

(6) Controls shall be observed until they are down and are unable to rise or stand under their own power. At this time they are euthanized and the time of death is recorded in hours. For a satisfactory test, the controls must reach this point with clinical signs of tetanus within 24 hours of each other and within an overall time of 60 to 120 hours. The clinical signs to be observed are increased muscle tonus, curvature of the spine, asymmetry of the body outline when the resting animal is viewed from above, generalized spastic paralysis, particularly of the extensor muscles, inability to rise from a smooth surface when the animal is placed on its side, or any combination of these signs. If the control guinea pigs do not respond in this manner, the entire test shall be repeated.

(7) Potency of an unknown antitoxin is determined by finding the mixture which will protect the test animal the same as the Standard Toxin-Antitoxin mixture. Test animals dying sooner than the controls indicate the unit value selected in that dilution was not present, whereas those living longer indicate a greater unit value.

[39 FR 16859, May 10, 1974. Redesignated at 39 FR 25463, July 11, 1974, and amended at 40 FR 760, Jan. 3, 1975; 40 FR 41996, Sept. 10, 1975; 43 FR 1479, Jan. 10, 1978; 50 FR 24905, June 14, 1985]

§ 113.252 Erysipelothrix Rhusiopathiae Antiserum.

Erysipelothrix Rhusiopathiae Antiserum shall be prepared from the

blood of horses hyper-immunized with the antigenic strains of *Erysipelothrix rhusiopathiae*. Each serial shall be tested for purity, safety, and potency as provided in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and subserial shall be tested for viable bacteria and fungi as prescribed in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b).

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested using the following two-stage test:

(1) In the first stage, each of 40 Swiss mice, each weighing 16 to 20 grams, shall be injected subcutaneously with 0.1 ml of antiserum. Twenty-four hours post-injection, the injected mice and 10 additional mice designated as controls shall be challenged subcutaneously with the same culture of *Erysipelothrix rhusiopathiae*.

(2) If less than eight of the 10 controls die from erysipelas within 7 days post-challenge, the test is invalid. All dead mice shall be examined to determine if the cause of death was *Erysipelothrix rhusiopathiae* infection.

(3) The antiserum injected mice shall be observed for 10 days post-challenge and all deaths recorded. The second stage shall be required when 7-10 of the anti-serum injected mice die in the first stage. The second stage shall be conducted in a manner identical to the first stage.

(4) The results of the test shall be evaluated according to the following table:

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total number of deaths for a satisfactory test	Cumulative total number of deaths giving an unsatisfactory test
		40	6 or less	11 or more.
		80	12 or less	13 or more.

[39 FR 16859, May 10, 1974. Redesignated at 39 FR 25463, July 11, 1974, as amended at 40 FR 20067, May 8, 1975; 40 FR 23989, June 4, 1975]

§ 113.253 Canine Distemper Hepatitis-Leptospira Antiserum.

The antiserum shall be prepared from blood of dogs hyperimmunized with canine distemper virus, canine hepatitis virus, and one or more leptospira species until the final product shall provide passive immunity against the disease agents named on the label. Each serial and subserial shall be tested for purity, safety, and potency as provided in this section. A serial or subserial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and subserial shall be tested for viable bacteria and fungi as prescribed in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b) and § 113.40.

(c) *Potency tests.* Bulk or final container samples of completed product from each serial shall be tested for potency as provided in this paragraph. Concentrated products shall be diluted to the equivalence of regular serum before testing. Standard antiserums and standard viruses, available upon request to Veterinary Services, shall be used.

(1) *Distemper fraction.* A virus neutralization test using chick embryo inoculation technique or acceptable tissue culture system shall be conducted.

(i) Serial threefold dilutions shall be made of the serum under test and the standard antiserum. A volume of each serial dilution of serum shall be mixed with an equal volume of standard virus. For use in the test, the standard virus shall be diluted to contain 100-1,000 ID_{50} per 0.1 ml.

(ii) A 1:2 dilution of the standard virus, as prepared for use in the test, shall be titrated in tenfold dilutions to determine the actual amount of virus used in the neutralization test. These dilutions shall be incubated along with serum/virus mixtures.

(iii) After 1 hour incubation at room temperature, 0.2 ml of each serum/virus mixture shall be inoculated onto

the chorioallantoic membrane of at least five chicken embryos 6-8 days old. The inoculated embryos shall be incubated at 35-37° C. for 6-7 days and the chorioallantoic membrances examined. Calculate the 50 percent end point of neutralization (ND_{50}) by the Reed and Muench or other acceptable statistical method.

(iv) The reciprocal of the ND_{50} dilution of the test serum divided by the reciprocal of the ND_{50} dilution of the standard serum is the test serum to standard ratio. A serial is unsatisfactory unless the average ratio of two tests is 0.67 or more.

(2) *Hepatitis fraction.* A virus neutralization test using canine kidney cell culture as the indicator system shall be conducted.

(i) Serial threefold dilutions shall be made of the antiserum under test and the standard antiserum. A volume of each serial dilution of serum shall be mixed with an equal volume of standard virus. The standard virus shall contain 100-1,000 $TCID_{50}$ per 0.1 ml.

(ii) A 1:2 dilution of the standard virus, as prepared for use in the test, shall be titrated in tenfold dilutions to determine the actual amount of virus used in the neutralization test. These dilutions shall be incubated along with serum/virus mixtures before inoculation of culture tubes.

(iii) After 1 hour incubation at room temperature, 0.2 ml of each serum/virus mixture shall be inoculated into five culture tubes containing dog kidney cell monolayers. The inoculated tubes shall be incubated at 35-37° C.

(iv) The tubes shall be observed daily for specific cytophathogenic changes from the 4th to 10th day post-inoculation. The test shall be terminated before the 10th day if additional cytopathogenic changes do not occur in virus titration tubes over a 48 hour period.

(v) Results shall be recorded and the 50 percent end point of neutralization (ND_{50}) calculated by the Reed and Muench or other acceptable statistical method.

(vi) The reciprocal of the ND_{50} dilution of the test serum divided by the reciprocal of the ND_{50} dilution of the standard serum is the test serum to standard ratio. A serial is unsatisfactory unless the average ratio of two tests is 0.67 or more.

(3) *Leptospira fraction.* Young adult hamsters, each weighing 40-50 grams, shall be used as test animals. For each species of leptospira antibody included in the product, each of at least five hamsters shall be injected with 60 percent of the minimum dose recommended on the label for 1 pound body weight of a dog and at least five additional hamsters shall be used as controls.

(i) Within 24 hours following injection, the five injected hamsters and the five control hamsters for each species of leptospira shall be challenged intraperitoneally with a suspension of virulent leptospira organisms representative of the species. A dose of 10-1,000 hamster LD_{50} shall be used. Both groups shall be observed for 14 days post-challenge and the results noted.

(ii) The test shall be conclusive if at least 80 percent of the controls in each group die from leptospirosis as demonstrated by acceptable cultural methods.

(iii) If the test is considered conclusive as provided in paragraph (c)(3)(ii) of this section, and less than 80 percent of the injected hamsters in a group remain normal during the observation period, the serial is unsatisfactory.

[39 FR 16860, May 10, 1974. Redesignated at 39 FR 25463, July 11, 1974, and amended at 39 FR 27431, July 29, 1974]

§ 113.254 Clostridium Perfringens Type C Antitoxin.

Clostridium Perfringens Type C Antitoxin shall be prepared from the blood of animals hyperimmunized with Clostridium Perfringens Type C toxin. Each serial shall be tested for purity, safety, and potency as provided in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b).

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested using the toxin-neutralization test for Beta Antitoxin provided in this paragraph.

(1) When used in this test, the following words and terms shall mean:

(i) *International antitoxin unit.* (I.U.) That quantity of Beta Antitoxin which reacts with L_0 and L_+ doses of Standard Toxin according to their definitions.

(ii) *L_0 dose.* The largest quantity of toxin which can be mixed with one unit of Standard Antitoxin and not cause sickness or death in injected mice.

(iii) *L_+ dose.* The smallest quantity of toxin which can be mixed with one unit of Standard Antitoxin and cause death in at least 80 percent of injected mice.

(iv) *Standard antitoxin.* The Beta Antitoxin preparation which has been standardized as to antitoxin unitage on the basis of the International *Clostridium perfringens* Beta Antitoxin Standard and which is either supplied by or acceptable to Veterinary Services. The antitoxin unit value shall be stated on the label.

(v) *Standard toxin.* The Beta toxin preparation which is supplied by or is acceptable to Veterinary Services.

(vi) *Diluent.* The solution used to make proper dilutions prescribed in this test. Such solution shall be made by dissolving 1 gram of peptone and 0.25 gram of sodium chloride in each 100 ml of distilled water; adjusting the pH to 7.2; autoclaving at 250° F. for 25 minutes; and storing at 4° C. until used.

(2) The antitoxin content of the test sample shall be determined as follows:

(i) Make a dilution of Standard Antitoxin to contain 10 International Units of antitoxin per ml.

(ii) Make one dilution of Standard Toxin to contain 10 L_0 doses per ml and make a second dilution of Standard Toxin to contain 10 L_+ doses per ml.

(iii) Dilute 1 ml of the test sample with 49 ml of diluent and combine 1 ml of this dilution with 1 ml of the Standard Toxin diluted to contain 10 L_0 doses.

(iv) Combine 10 International Units of Standard Antitoxin with 10 L_0 doses of diluted Standard Toxin and combine 10 International Units of Standard Antitoxin with 10 L_+ doses of diluted Standard Toxin.

(v) Neutralize all toxin-antitoxin mixtures at room temperature for 1 hour and hold in ice water until injections of mice can be made.

(vi) Five Swiss white mice, each weighing 16-20 grams, shall be used for each toxin-antitoxin mixture. A dose of 0.2 ml shall be injected intravenously into each mouse. Conclude the test 24 hours post-injection and record all deaths.

(3) Test Interpretation. (i) If any mice inoculated with the mixture of 10 International Units of Standard Antitoxin and 10 L_0 doses of Standard Toxin die, the results of the test are inconclusive and shall be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(ii) If less than 80 percent of the mice inoculated with the mixture of 10 International Units of Standard Antitoxin and 10 L_+ doses of Standard Toxin die, the results of the test are inconclusive and shall be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(iii) If any mice inoculated with the mixture of Clostridium Perfringens Type C Antitoxin diluted 1:50 and 10 L_0 doses of Standard Toxin die, the antitoxin is considered to contain less than 500 International Unit per ml and the serial is unsatisfactory.

[39 FR 16859, May 10, 1974. Redesignated at 39 FR 25463, July 11, 1974]

§ 113.255 Clostridium Perfringens Type D Antitoxin.

Clostridium Perfringens Type D Antitoxin shall be prepared from the blood of animals hyperimmunized with Clostridium Perfringens Type D toxin. Each serial shall be tested for purity, safety, and potency as provided in this section. A serial found unsatisfactory by any prescribed test shall not be released.

(a) *Purity test.* Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Bulk or final container samples of completed product from each serial shall be tested for safety as provided in § 113.33(b).

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested using the toxin-neutralization test for Epsilon Antitoxin provided in this paragraph.

(1) When used in this test, the following words and terms shall mean:

(i) *International antitoxin unit.* (I.U.) That quantity of Epsilon Antitoxin which reacts with L_0 and L_+ doses of Standard Toxin according to their definitions.

(ii) *L_0 dose.* The largest quantity of toxin which can be mixed with one-tenth unit of Standard Antitoxin and not cause sickness or death in injected mice.

(iii) *L_+ dose.* The smallest quantity of toxin which can be mixed with one-tenth unit of Standard Antitoxin and cause death in at least 80 percent of injected mice.

(iv) *Standard antitoxin.* The Epsilon Antitoxin preparation which has been standardized as to antitoxin unitage on the basis of the International *Clostridium perfringens* Epsilon Antitoxin Standard and which is either supplied by or acceptable to Veterinary Services. The antitoxin unit value shall be stated on the label.

(v) *Standard toxin.* The Epsilon toxin preparation which is supplied by or is acceptable to Veterinary Services.

(vi) *Diluent.* The solution used to make proper dilutions prescribed in this test. Such solution shall be made by dissolving 1 gram of peptone and 0.25 gram of sodium chloride in each 100 ml of distilled water; adjusting the pH to 7.2; autoclaving at 250° F. for 25 minutes; and storing at 4° C. until used.

(2) The antitoxin content of the test sample shall be determined as follows:

(i) Make a dilution of Standard Antitoxin to contain 1 International Unit of antitoxin per ml.

(ii) Make one dilution of Standard Toxin to contain 10 L_0 doses per ml and make a second dilution of Standard Toxin to contain 10 L_+ doses per ml.

(iii) Dilute 1 ml of the test sample with 33 ml of diluent and combine 1 ml of this dilution with 1 ml of the Standard Toxin diluted to contain 10 L_0 doses.

(iv) Combine 1 International Unit of Standard Antitoxin with 10 L_0 doses of Standard Toxin and combine 1 International Unit of Standard Antitoxin with 10 L_+ doses of Standard Toxin.

(v) Neutralize all toxin-antitoxin mixtures at room temperature for 1 hour, and hold in ice water until injections of mice can be made.

(vi) Five Swiss white mice, each weighing 16–20 grams, shall be used for each toxin-antitoxin mixture. A dose of 0.2 ml shall be injected intravenously into each mouse. Conclude the test 24 hours post-injection and record all deaths.

(3) Test Interpretation. (i) If any mice inoculated with the mixture of 1 International Unit of Standard Antitoxin and 10 L_0 doses of Standard Toxin die, the results of the test are inconclusive and shall be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(ii) If less than 80 percent of the mice inoculated with mixture of 1 International Unit of Standard Antitoxin and 10 L_+ doses of Standard Toxin die, the results of the test are inconclusive and shall be repeated: *Provided,* That, if the test is not repeated, the serial shall be declared unsatisfactory.

(iii) If any mice inoculated with the mixture of Clostridium Perfringens Type D Antitoxin diluted 1:34 and 10 L_0 doses of Standard Toxin die, the antitoxin is considered to contain less than 34 International Units per ml and the serial is unsatisfactory.

[39 FR 16859, May 10, 1974. Redesignated at 39 FR 25463, July 11, 1974, as amended at 40 FR 760, Jan. 3, 1975]

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

Sec.
114.1 Applicability.
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AUTHORITY: 21 U.S.C. 151-158.

SOURCE: 39 FR 16869, May 10, 1974, unless otherwise noted.

§ 114.1 Applicability.

Unless otherwise authorized by the Deputy Administrator, all biological products prepared for shipment or delivered for shipment from one State or territory or the District of Columbia to another State or territory or the District of Columbia shall be prepared in accordance with the regulations in this part. The licensee or permittee shall adopt and enforce all necessary measures and shall comply with all directions the Deputy Administrator prescribes for carrying out such regulations.

§ 114.2 Products not prepared under license.

(a) When an establishment license is issued, if biological products which were not prepared in compliance with the regulations are in the establishment, such products shall not be shipped or delivered for shipment or otherwise dealt with as having been prepared under such regulations.

(b) When an establishment license is issued for an interim period not to exceed 4 years, the establishment may continue preparing certain specified unlicensed biological products with the permission of the Deputy Administrator; *Provided*, That:

(1) Such unlicensed products have been prepared in the establishment within the 12 months prior to issuance of the establishment license.

(2) Such unlicensed products are not distributed interstate, do not bear a U.S. Veterinary license number, and are not otherwise represented in any manner as having met the requirements for licensure.

(3) All products, whether licensed or unlicensed, are prepared in locations indicated in legends filed in accordance with Part 108 of this Subchapter.

(4) A description of methods of preparation and testing of each unlicensed product are filed with Veterinary Services.

(5) Records are maintained in accordance with §§ 116.1 and 116.2 and include all products, whether licensed or unlicensed.

(6) Reports prescribed in § 116.5 are submitted for all products, whether licensed or unlicensed.

(7) No new unlicensed biological products are prepared in the licensed establishment after issuance of the establishment license except as provided in § 103.1

(8) The licensee either achieves licensure of all unlicensed products by the close of the interim period or discontinues producing and removes from the licensed establishment any product which is not licensed.

(c) Except as provided in Part 103 of this subchapter, a biological product shall not be prepared in a licensed establishment unless the person to whom the establishment license is issued holds an unexpired, unsuspended, and unrevoked product license issued by the Deputy Administrator to prepare such biological product.

[39 FR 16869, May 10, 1974, as amended at 41 FR 38496, Sept. 10, 1976; 50 FR 50764, Dec. 12, 1985]

§ 114.3 Separation of establishments.

(a) Each licensed establishment shall be separate and distinct from any other establishment in which a biological product is prepared.

(b) No biological products authorized to be prepared in a licensed establishment shall be prepared in whole or in part by another licensed establishment except as provided in paragraphs (c) and (d) of this section.

(c) When a partially prepared biological product cannot be completed at a licensed establishment due to failure of essential equipment, the Deputy Administrator may authorize the use of similar equipment at another licensed establishment: *Provided*, That, such authorization shall be limited to the duration of the emergency and to the phase of production affected by the equipment failure.

(d) Partially prepared products or serials of completed products for further manufacture may be moved from one licensed establishment to another licensed establishment, imported under the provisions of § 104.5, or moved from a licensed establishment for purpose of being exported under conditions prescribed in an Outline of Production filed with Veterinary Services. Licensed products or products imported for distribution and sale may be prepared and recommended for final use, for further manufacturing purposes, or both. All serials shall be subject to the requirements for testing and release specified in § 113.5 or § 113.10 and to the requirements for identification specified in § 114.4.

[39 FR 16869, May 10, 1974, as amended at 40 FR 46093, Oct. 6, 1975; 49 FR 45846, Nov. 21, 1984]

§ 114.4 Identification of biological products.

Suitable tags or labels of a distinct design shall be used for identifying all ingredients used in the preparation of biological products, all component parts to be combined to form a biological product, all biological products while in the course of preparation and all completed biological products held in storage at licensed establishments: *Provided*, That, if such ingredients, components, or biological products are not so identified, they shall be disposed of as provided in § 114.15.

§ 114.5 Micro-organisms used as seed.

Micro-organisms used in the preparation of biological products at licensed establishments shall be free from the causative agents of other diseases or conditions. A complete record of such micro-organisms shall be kept currently correct and a list submitted to Veterinary Services upon request of the Deputy Administrator.

(Approved by the Office of Management and Budget under control number 0579-0059)

[39 FR 16869, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983]

§ 114.6 Mixing biological products.

Each biological product, when in liquid form, shall be mixed thoroughly in a single container. During bottling operations, the product shall be constantly mixed sufficient to maintain physical uniformity of the entire fill. A serial number, with any other markings that may be necessary for ready identification of the serial, shall be applied to identify it with the records of preparation and labeling.

§ 114.7 Personnel at licensed establishments.

(a) Each licensee shall designate a person(s) to make all official contacts with Veterinary Services on matters pertaining to the preparation of biological products under the Virus-Serum-Toxin Act. The licensee shall file three copies of biographical summary with Veterinary Services for such designated person and for each person responsible for any phase of preparation of a biological product.

(b) All personnel employed in the preparation of biological products at a licensed establishment shall be competent in good laboratory techniques through education or training, or both, so as to consistently prepare high quality products.

(c) All biological products prepared at licensed establishments shall be prepared and handled with due sanitary precautions. Good sanitary measures shall be practiced at all times by all personnel involved in such preparation and handling of biological products.

(1) The clothing worn by persons while preparing biological products shall be clean. All persons, immediately before entering laboratory rooms of a licensed establishment, shall change their outer clothing or effectively

cover the same with gowns or other satisfactory clean garments.

(2) Unsanitary practices such as, but not limited to, eating, smoking, or expectorating on the floors or otherwise creating a nuisance in any room, compartment, or place in which biological products are prepared, handled, or stored at licensed establishments are prohibited.

(Approved by the Office of Management and Budget under control number 0579-0013)

[39 FR 16869, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983]

§ 114.8 Outline of Production required.

An Outline of Production shall be on file with Veterinary Services for each licensed biological product or for each biological product authorized to be imported into the United States for Distribution and Sale. Preparation of a biological product in a licensed establishment shall be in accordance with the Outline of Production for such product filed with Veterinary Services as provided in this section, but subject to changes as may be required under § 114.8(f).

(a) The Outline of Production shall be prepared as prescribed in § 114.9 and submitted to Veterinary Services for filing. When objectionable features, if any, are corrected and no further exceptions are taken by Veterinary Services to an Outline of Production for a biological product, such Outline of Production shall be approved for filing.

(b) Each page shall be stamped as filed on the date such action was taken in the bottom right hand corner. Although the filed outline may be referred to as an approved outline, approval for filing constitutes no endorsement by Veterinary Services of such biological product or the methods and procedures used to prepare such biological product.

(c) The original and two copies shall be retained by Veterinary Services and the remaining copies returned.

(d) Each licensee shall review each Outline of Production for accuracy and sufficiency not less frequently than once a year. Revisions necessary to bring an Outline of Production into compliance with the regulations shall be submitted to Veterinary Services.

(e) When a list of licensed products to be continued in production at a licensed establishment is requested by the Deputy Administrator in accordance with § 102.5(d) of this subchapter, the licensee shall supplement the list with information for each product as follows:

(1) The Outline of Production currently being used shall be identified as to the date when last revised and filed with Veterinary Services and the date of the last review made by the licensee.

(2) The Outline of Production to be kept in the active file shall be designated. If more than one has been filed for a product, only the Outline of Production currently being used shall be included.

(f) The Deputy Administrator may, upon the basis of information not available to him at the time the current Outline of Production for a biological product was filed, object to the methods or procedures being used in the preparation of such biological product and notify the licensee to modify the filed Outline of Production to eliminate such objections. If the licensee does not comply with the notice, the Deputy Administrator may, after affording opportunity for a hearing to the licensee, suspend the product license for the biological product involved; in which case, the licensee shall not prepare such product until subsequent notice of withdrawal of the suspension is given to the licensee.

(Approved by the Office of Management and Budget under control number 0579-0013)

[39 FR 16869, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983]

§ 114.9 Outline of Production guidelines.

Each Outline of Production shall be prepared in accordance with the applicable directions provided in this section.

(a) *General requirements.* (1) The original and not more than four copies of each Outline of Production or special outline or revised pages of either shall be prepared on heavy paper

(8.5" x 11") of a type receptive to permanent stamp ink.

(2) The name of the biological product (or component), the establishment license number, and the date prepared shall appear on a front cover page and each page of the Outline of Production or special outline. The name of the licensee (or foreign manufacturer) shall appear on the front cover page.

(3) The pages shall be numbered in the upper center. At least 1½ inch margin shall be left at the top of the first page and a 2 inch margin at the bottom of each page for the Veterinary Services stamp.

(4) Amended pages shall be numbered the same as those being superseded. They shall bear the date prepared and refer to the date on the pages being superseded. If one replacement page supersedes more than one page, the new page shall indicate same, but if several replacement pages are added to supersede one page, the page number followed by letters shall be used.

(5) The last page of the original and one copy of either a new or a completely rewritten Outline of Production and each page revised separately shall be signed in the lower left corner by the authorized representative of the licensee (or foreign producer). Stamped or facsimile signatures are not acceptable.

(6) A summary of changes shall appear on an attached page and refer to each page, paragraph, or subparagraph being changed.

(7) Transmittal forms shall be used for the original and subsequent revisions. Blank forms shall be available upon request to Veterinary Services.

(b) *Special outline.* An outline describing the preparation of a component of a biological product or an operation performed in the preparation of a biological product may be required if such special outline could be referred to in Outlines of Production to eliminate repetition. Each special outline shall be identified by number and shall not be used until accepted and filed by Veterinary Services.

(c) Outline of Production for antiserum, antitoxin, and normal serum shall be written according to the following:

OUTLINE GUIDE FOR PRODUCTION OF ANTISERUM AND ANTITOXIN AND NORMAL SERUM

License No. Name of Product Date

I. *Serum animals.* A. Species, conditions, age, and general health.

B. Examination, preparation, care, quarantine, tests, and treatment of animals before injections are started.

C. Holding, handling, exercising, and monitoring the condition of animals after injections are started.

II. *Antigens.* A. Composition and character of the antigen.

1. Micro-organisms.

2. Source and date of accession of each micro-organism.

3. Strains.

4. Proportions of each micro-organism and strain.

B. Identification methods used for each micro-organism and frequency with which these methods are applied.

C. Virulence and purity of cultures or antigen and the determination and maintenance thereof. Range of subcultures or passages to be used in production.

D. Attenuation, if any, before use for production purposes.

E. Character, size, and shape of containers used for growing micro-organisms.

F. Media used for stock, seed, and antigen cultures (composition and reaction of). May refer to a special outline by number.

G. Preparation of the antigen or toxin and toxoid. Complete and full description of each step and its manner of accomplishment and number these steps in sequence. Include all tests for each antigen, and the specifications for character, identity, virulence, concentration, and standardization.

III. *Immunization of animals.* A. Outline fully with special attention given to the following:

1. Character and dose of the antigen.

2. Method and frequency of injections.

3. Time required for immunization or hyperimmunization.

4. Preliminary bleedings and tests, if any, to ascertain quality of serum.

5. All other similar matters, including treatments between bleedings.

B. Period of time elapsing between last injection and first bleeding; and between bleedings.

C. Technique of bleeding operations; volume of blood collected at each bleeding; and period of rest.

IV. *Preparation of the biological product.* A. Describe fully and show each step of preparation from the first bleeding to the completion of the preserved product in bulk containers prior to filling of final containers.

B. Composition of the preservative and proportions used. Indicate at which step of production, and the method used in adding the preservative.

C. Agglutination and complement-fixation titers and the methods of their determinations.

D. Disposition of unsatisfactory biological products and infective materials not used in production.

E. Assembly of units to make a serial; volume of the average serial; and the volume of the maximum serial.

V. *Testing.* Indicate the stages in the preparation of the biological product at which samples are collected. Refer to all applicable Standard Requirements. Outline all additional tests in detail and state minimum requirements for each satisfactory test.

A. Purity.

B. Safety.

C. Potency.

D. Other tests.

VI. *Post preparatory steps.*

A. Form and size of final containers in which the product is to be distributed.

B. Methods and techniques of filling final containers. Volume of fill for each size final container.

C. Collection, storage, and submission of representative samples. Indicate at which steps in the production these samples are taken.

D. Expiration date based on the earliest date of harvest and the date of the last satisfactory potency test.

E. Use, dosage, and route of administration for each animal species for which it is recommended.

F. Include any additional pertinent information.

(d) Outline of Production for *vaccines, bacterins, antigens,* and *toxoids* shall be written according to the following:

OUTLINE GUIDE FOR VACCINES, BACTERINS, ANTIGENS, AND TOXOIDS

License No. Name of Product Date

I. *Composition, etc., of the product.* A. Micro-organisms used. Give the isolation and passage history.

B. Source and date of accession of each micro-organism.

C. Strains.

D. Proportions of each strain.

II. *Cultures.* A. Brief description of methods of identifying each micro-organism and the frequency with which these methods are applied.

B. Virulence and purity of cultures and the determination and maintenance thereof. Range of subcultures or passages to be used in production.

C. Composition and reaction of media used for seed and production cultures. Include the source of eggs, tissue, or cell cultures, and the tests to determine that eggs, tissues, and cells are free of contamination.

D. Character, size, and shape of containers used for growing cultures.

E. Storage conditions of seed cultures.

F. Methods of preparing suspensions for seeding or inoculation.

G. Technique of inoculating (1) seed media; (2) production media. Titer or concentration of inoculum, and the volume of medium for each size and type of culture container.

H. Period of time and conditions for incubation and degree of temperature used for each micro-organism or group of micro-organisms.

I. Character and amount of growth; observation as to contamination of growth.

J. Method of attenuation, if any, before used for production purposes.

III. *Harvest.* A. Handling and preparation of cultures and media (including eggs) before removal of micro-organisms or tissues for production purposes.

B. Minimum and maximum period of time elapsing from time of inoculation until harvest.

C. Technique of harvesting micro-organisms or tissues (specify) for production purposes.

D. Specifications for acceptable harvest material.

E. Handling of discarded material not used in production.

F. Include any additional pertinent information.

IV. *Preparation of the product.* Describe fully and show each step of preparation from harvest of antigen containing tissues or production cultures to the completion of the finished product in final containers. In describing the preparation of the product, emphasize the following:

A. Method of inactivation, attenuation, or detoxification.

B. Composition of preservative, adjuvant or stabilizer, and proportions used stated in such a manner that the concentration can be calculated; stage and method of addition.

C. Method and degree of concentration.

D. If product is standardized to give concentration of antigen, show procedures and calculations.

E. 1. Assembly of units to make a serial (illustrate by example).

2. Volume of average serial.

3. Volume of maximum serial.

4. Any other pertinent information.

F. Volume of fill for each size vial. Type of vial if unusual.

G. Method and technique of filling and sealing of final containers.

H. Desiccation, including moisture control. Give maximum percent moisture.

I. Amount of antigenic material per dose or doses in final container.

V. *Testing.* Indicate the stages in the preparation of the biological product at which the samples are collected. Refer to all applicable Standard Requirements. Outline all additional tests in detail and state the minimum requirement for each satisfactory test.

A. Purity.
B. Safety.
C. Potency.
D. Moisture, if desiccated.
E. Any other tests.

VI. *Post preparatory steps.* A. Form and size of final containers in which the product is to be distributed.

B. Collection, storage, and submission of representative samples. Indicate at which steps in the production these samples are taken.

C. Expiration date based on the earliest date of harvest and the date of the last satisfactory potency test. If applicable, give the date of lyophilization.

D. Use, dosage, and route of administration for each animal species for which the biological product is recommended.

(e) Outlines of Production for allergenic extracts shall be written according to the following:

OUTLINE GUIDE FOR ALLERGENIC EXTRACTS

License No. Name of Product Date

I. *Composition of the product.* A. Source and type of raw material.

B. Weight/volume concentration.

II. *Preparation of the product.* A. Describe fully and show each step of preparation to the completion of the finished product in true containers. In describing the preparation of the product, emphasize the following:

1. Method of extraction.
2. Composition of preservative, adjuvant or stabilizer, and proportions used; stage and method of addition.
3. Method and degree of concentration.
4. Standardization of the product.
5. (a) Assembly of units to make a serial.
(b) Volume of average serial.
(c) Maximum serial.
6. Volume of fill for each size vial.
7. Method and technique of filling and sealing of final containers.
8. Amount material per dose or doses in final container.

III. *Testing.* Indicate the stages in the preparation of the biological product at which the samples are collected. Refer to all applicable Standard Requirements. Outline all additional tests in detail and state the minimum requirement for each satisfactory test.

A. Purity.
B. Safety.
C. Potency.
D. Any other tests.
E. Include any additional pertinent information.

IV. *Post preparatory steps.* A. Form and size of final containers in which the product is to be distributed.

B. Collection, storage, and submission of representative samples. Indicate at which steps in the production these samples are taken.

C. Expiration date based on the earliest date of harvest and the date of the last satisfactory potency test.

D. Use, dosage, and route of administration for each animal species for which the biological product is recommended.

(Approved by the Office of Management and Budget under control number 0579-0013)

[39 FR 16869, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983]

§ 114.10 Antibiotics as preservatives.

Antibiotics are authorized for use as preservatives for biological products if used within the limitations as to kinds and amounts prescribed in this section.

(a) When an antibiotic or combination of antibiotics, with or without a fungistat is to be used in the preparation of a biological product, the kind(s) and amount(s) of each shall be specified in the outline for such product in such a way that the concentration in the final product may be calculated. Except as may be approved by the Deputy Administrator, only those individual antibiotics or combinations of antibiotics listed in paragraphs (b) and (c) of this section shall be used.

(b) Permitted individual antibiotics:

(1) The antibiotic level of a specified individual antibiotic in one ml. of a biological product, when prepared as recommended for use, shall not exceed the amounts listed in this paragraph: *Provided,* That in the case a desiccated biological product is to be used with an indefinite quantity of water or other menstruum, the determination shall be based on 30 ml. per 1,000 dose vial or equivalent.

(2) Except as prescribed in paragraph (c) of this section, only one antibiotic shall be used as a preservative in a biological product. The kind and

maximum amount per ml. of such antibiotic shall be restricted to:

Amphotericin B	2.5 mcg.
Nystatin (Mycostatin)	30.0 units
Tetracyclines	30.0 mcg.
Penicillin	30.0 units
Streptomycin	30.0 mcg.
Polymyxin B	30.0 mcg.
Neomycin	30.0 mcg.
Gentamicin	30.0 mcg.

(c) Permitted combinations:

(1) Penicillin and streptomycin.

(2) Either amphotericin B or nystatin, but not both, may be used with one of the other antibiotics listed in paragraph (b) of this section, or with a combination of penicillin and streptomycin, or with a combination of polymyxin B and neomycin.

(3) The maximum amount of each antibiotic in a combination shall be the amount prescribed for such antibiotic in paragraph (b) of this section.

(d) Antibiotics used in virus seed stock purification are not restricted as to kind or amounts provided carryover into the final product is controlled and specified in outlines of production.

§ 114.11 Storage and handling.

Biological products at licensed establishments shall be protected at all times against improper storage and handling. Completed product shall be kept under refrigeration at 35° to 45° F. (2° to 7° C.) unless the inherent nature of the product makes storage at a different temperature advisable, in which case, the proper storage temperature shall be specified in the filed Outline of Production. All biological products to be shipped or delivered shall be securely packed.

§ 114.12 Expiration date required.

Each serial or subserial of biological product prepared in a licensed establishment shall be given an expiration date determined in accordance with the requirements provided in § 114.13 or § 114.14. A licensed biological product shall be considered worthless under the Virus-Serum-Toxin Act subsequent to the expiration date appearing on the label.

[41 FR 44687, Oct. 12, 1976]

§ 114.13 Expiration date determination.

Unless otherwise provided for in a Standard Requirement of filed Outline of Production, the expiration date for each product shall be computed from the date of the initiation of the potency test. Prior to licensure, stability of each fraction shall be determined by methods acceptable to Veterinary Services. Expiration dates based on this stability data shall be confirmed as follows:

(a) *Products consisting of viable organisms.* Each serial shall be tested for potency at release and at the approximate expiration date until a statistically valid stability record has been established.

(b) *Nonviable biological products.* Each serial presented in support of licensure shall be tested for potency at release and at or after the dating requested.

(c) Subsequent changes in the dating period for a product may be granted, based on statistically valid data submitted to support a revision of the Outline of Production.

[50 FR 24903, June 14, 1985]

§ 114.14 Extension of expiration date for a serial or subserial.

(a) Unless otherwise provided for in a filed Outline of Production for the product, the expiration date shall not be extended:

(1) If all fractions of the product are not evaluated for potency by tests designated in the filed Outline of Production for such product in accordance with § 113.4(b) of this subchapter.

(2) For any serial or portion of any serial which has left licensed premises: *Provided,* That product which has been shipped from one licensed premises to another licensed premises shall be exempt from this requirement.

(3) For a serial or portion of a serial if the expiration date has been extended previously, unless otherwise authorized in accordance with § 114.1.

(b) An extension of the expiration date may be granted by Veterinary Services if a request from the licensee is substantiated by valid test data which demonstrate the potency of the product meets or exceeds the requirements for release. The new expiration date shall be calculated from the date the latest satisfactory potency test was initiated. The extension of the expiration date shall not exceed the maximum dating allowed in the filed Outline of Production.

(1) Serials are approved for redating under the condition that Veterinary Services may require the firm to retest the redated serial for potency during the extended dating period and if found unsatisfactory require it be removed from the market by the licensee.

[50 FR 24903, June 14, 1985]

§ 114.18 Reprocessing of biological products.

The Deputy Administrator may authorize a licensee to reprocess a serial of completed product subject to the conditions prescribed in this section.

(a) Reprocessing shall not include any method or procedure which would be deleterious to the product.

(b) All appropriate tests for purity, safety, potency, and efficacy for the product shall be conducted on the reprocessed product. A serial found unsatisfactory by a required test shall not be released.

(c) The reprocessed serial shall be identified by a new serial number and the records for the serial shall accurately reflect the action taken.

(d) Test samples of the reprocessed serial and test reports for all tests conducted shall be submitted to Veterinary Services. The licensee shall not release the serial until notified by Veterinary Services that the serial is eligible for release.

[50 FR 24904, June 15, 1985]

§ 114.15 Disposal of unsatisfactory products and byproducts.

All biological products found to be unsatisfactory for marketing, all biological products which have become worthless subsequent to the expiration date, all refuse, other materials deemed unsatisfactory for production purposes, all carcasses (part or whole) of production or test animals, and any undesirable byproducts of manufacture shall be disposed of as may be required by the Deputy Administrator.

[41 FR 44687, Oct. 12, 1976]

§ 114.16 Producing subsidiaries.

A serial or subserial of a biological product may be produced jointly by a licensee and one or more subsidiaries, or by two or more subsidiaries. The exact amount of each serial or subserial credited to each participating producer shall be determined at the time of labeling and packaging and shall be noted in the records for such serial or subserial.

[40 FR 46093, Oct. 6, 1975]

§ 114.17 Rebottling of biological products.

The Deputy Administrator may authorize the rebottling of a completed product in liquid form subject to the conditions prescribed in this section.

(a) All or part of a serial which has not left the licensed establishment may be aseptically returned to the mixing tank, thoroughly mixed, and rebottled in new final containers.

(b) The rebottled product shall be adequately identified by serial number or subserial number, as the case may be.

(c) Required purity tests for final container samples of the product shall be conducted on new samples selected from the rebottled product (serial or subserials). Rebottled product found to be unsatisfactory by such tests shall not be released.

(d) New test samples from each serial or subserial and copies of test reports of all tests conducted on the rebottled product shall be submitted to Veterinary Services.

(e) The licensee shall not release the rebottled product unless notified by Veterinary Services that such product is eligible for release. Production records shall show the results of all tests conducted and shall accurately reflect the actions taken.

§ 114.18 Reprocessing of biological products.

The Deputy Administrator may authorize a licensee to reprocess a serial of completed product in liquid form subject to the conditions prescribed in this section.

(a) Reprocessing shall not include any method or procedure which would be deleterious to the product.

(b) The serial shall be uniformly reprocessed and thoroughly mixed prior to bottling in final containers.

(c) All required tests for purity, safety, potency, and efficacy for the product shall be conducted on the reprocessed product. A serial found unsatisfactory by a required test shall not be released.

(d) The reprocessed serial shall be identified by a new serial number and the records for the serial shall accurately reflect the action taken.

(e) Test samples of the reprocessed serial and test reports for all tests conducted shall be submitted to Veterinary Services. The licensee shall not release the serial until notified by Veterinary Services that the serial is eligible for release.

PART 115—INSPECTIONS

Sec.
115.1 Inspections of licensed establishments.
115.2 Inspections of biological products.

§ 115.1 Inspections of licensed establishments.

(a) Any inspector shall be permitted to enter any establishment licensed under the regulations in Parts 101 through 117 of this subchapter at any hour during the day or night, and shall be permitted to inspect, without previous notification, the entire premises of the establishment, including all buildings, compartments, and other places, all biological products, and organisms and vectors in the establishment, and all equipment, such as chemicals, instruments, apparatus, and the like, and the methods used in the manufacture of, and all records maintained relative to, biological products produced at such establishment.

(b) Each inspector will be furnished with a numbered official badge or identification card, which he shall not allow to leave his possession. Either shall be sufficient identification to entitle him to admittance at all regular entrances and to all parts of the licensed establishment and premises and to any place at any time for the purpose of making an inspection pursuant to paragraph (a) of this section.

(37 Stat. 823-833; 21 U.S.C. 151-158)

[37 FR 28131, Dec. 21, 1972]

§ 115.2 Inspections of biological products.

All biological products, the containers of which bear United States veterinary license numbers or United States veterinary permit numbers or other marks required by these regulations may be inspected at any time or place. If, as a result of such inspection, it appears that any such product, even those prepared in a licensed establishment or imported under permit issued by the Secretary, is worthless, contaminated, dangerous, or harmful, the Secretary shall give notice thereof to the manufacturer or importer and to any jobbers, wholesalers, dealers, or other persons known to have any of such product in their possession. Unless and until the Secretary shall otherwise direct, no persons so notified shall thereafter sell, barter, or exchange any such product in any place under the jurisdiction of the United States or ship or deliver for shipment any such product from any State, Territory, or the District of Columbia. However, failure to receive such notice shall not excuse any person from compliance with the Virus-Serum-Toxin Act.

(37 Stat. 823-833, 21 U.S.C. 151-158)

[37 FR 28131, Dec. 21, 1972]

PART 116—RECORDS

Sec.
116.1 Applicability and general considerations.
116.2 Inventory and disposition records.
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116.4 Sterilization and pasteurization records.
116.5 Reports.
116.6 Animal records.
116.7 Test records.
116.8 Completion and retention of records.

AUTHORITY: 37 Stat. 832-833; 21 U.S.C. 151-158.

§ 116.1 Applicability and general considerations.

Each licensee and each foreign manufacturer of biological products imported into the United States shall maintain detailed records of information necessary to give a complete accounting of the activities within each establishment. Such records shall include, but shall not be limited to the items enumerated in this part.

(a) Records shall be made concurrently with the performance of successive steps in the preparation of a biological product. Such records shall include the date and where critical, the time that each essential step was taken, the identity and quantity of ingredients added or removed at each step, and any loss or gain from start to finish in such preparation.

(b) Records shall be legible and indelible; shall be as detailed as necessary for a clear understanding of each step by one experienced in the preparation of biological products; and shall be verified by initials or signature of the person immediately responsible for the action taken.

(c) Records (other than disposition records) required by this part shall be completed by the licensee or the foreign manufacturer, as the case may be, before any portion of a serial of any product shall be marketed in the United States or exported.

(Approved by the Office of Management and Budget under control number 0579-0059)

(44 U.S.C. 3506)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983]

§ 116.2 Inventory and disposition records.

(a) Records shall show the quantity and location of each biological product being prepared, in storage, and in distribution channels.

(b) Detailed disposition records, in a form satisfactory to the Deputy Administrator, shall be maintained by each licensee, each distributor, and each permittee showing the sale, shipment, or other disposition made of the biological products handled by such person.

(Approved by the Office of Management and Budget under control number 0579-0059)

(44 U.S.C. 3506)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983]

§ 116.3 Label records.

(a) Each licensee and permittee shall maintain a list of all approved labels currently being used. Each label shall be identified as to:

(1) Name and product code number as it appears on the product license or permit for the product;

(2) Where applicable, the size of the package (doses, ml, cc, or units) on which the label shall be used;

(3) Label number and date assigned; and

(4) Name of licensee or subsidiary appearing on the label as the producer.

(b) All labels printed shall be accounted for and an inventory maintained.

Records shall include the disposition of such labels including those not used in labeling a product.

(Approved by the Office of Management and Budget under control number 0579-0059)

(44 U.S.C. 3506)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983]

§ 116.4 Sterilization and pasteurization records.

Records shall be made by means of automatic recording devices or an equivalent accurate and reliable system. Such records shall be identified with the ingredients, equipment, or biological product subjected to sterilization or pasteurization.

(Approved by the Office of Management and Budget under control number 0579-0059)

(44 U.S.C. 3506)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983]

§ 116.5 Reports.

When required by the Deputy Administrator, reports containing accurate information of production activities in each establishment by the licensee or the foreign manufacturer whose products are either being offered for importation or being imported into the United States, as the case may be, shall be prepared and forwarded to Veterinary Services. Records necessary to make such reports shall be maintained in each establishment.

(Approved by the Office of Management and Budget under control number 0579-0059)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983]

§ 116.6 Animal records.

Complete records shall be kept for all animals at a licensed establishment. Results of tests performed, antigens or treatment administered, maintenance and production records, disposition records, necropsy records, if any, and all other pertinent records shall be included.

(Approved by the Office of Management and Budget under control number 0579-0059)

(44 U.S.C. 3506)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983]

§ 116.7 Test records.

Detailed records of all tests conducted on each serial and each subserial shall be maintained by the licensee. Summaries of such tests shall be prepared from such records and submitted to Veterinary Services prior to release of the serial or subserial. Blank forms for such summaries shall be available from Veterinary Services upon request.

(Approved by the Office of Management and Budget under control number 0579-0013)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983]

§ 116.8 Completion and retention of records.

All records (other than disposition records) required by this part shall be completed by the licensee or the foreign manufacturer, as the case may be, before any portion of a serial of any product may be marketed in the United States or exported. All records shall be retained for a period of 2 years after the expiration date of the product involved and for such longer period as may be required by the Deputy Administrator in specific cases.

(Approved by the Office of Management and Budget under control number 0579-0059)

(44 U.S.C. 3506)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983]

PART 117—ANIMALS AT LICENSED ESTABLISHMENTS

Sec.

117.1 Applicability.
117.2 Animal facilities.
117.3 Admittance of animals.
117.4 Test animals.
117.5 Segregation of animals.
117.6 Removal of animals.

AUTHORITY: 37 Stat. 832-833 (21 U.S.C. 151-158).

SOURCE: 38 FR 15499, June 13, 1973, unless otherwise noted.

§ 117.1 Applicability.

(a) All animals used in licensed establishments in the preparation or testing of biological products shall meet the regulations in this subchapter and special requirements as may be prescribed by the Deputy Administrator to prevent the preparation, sale, and distribution of worthless, contaminated, dangerous, or harmful biological products.

(b) Unless otherwise authorized or directed by the Deputy Administrator, animals used in the preparation or testing of biological products shall be admitted to and maintained at the licensed establishment and ultimately disposed of in accordance with the regulations in this part, and with the Act of August 24, 1966 (Pub. L. 89-544) as amended by the Animal Welfare Act of 1970 (Pub. L. 91-579) and the regulations in Parts 1, 2, and 3 of this chapter. Personnel who supervise the care and welfare of such animals shall be qualified by education, training, and experience to carry out the regulations in this part.

§ 117.2 Animal facilities.

Animal facilities shall comply with the requirements provided in Part 108 of this chapter.

§ 117.3 Admittance of animals.

(a) No animal which shows clinical signs or other evidence of disease shall be admitted to the premises of licensed establishments, except as provided in paragraphs (d) and (e) of this section. The health status of all animals offered for admission shall be determined by or under the direction of a veterinarian prior to admission. If the determination cannot be made prior to admission, the animals shall be kept separate from animals already on the premises and in a quarantine area to be provided by the licensee for this purpose until the animal's health status is determined.

(b) If special test requirements for admittance of the animals are specified in the Outline of Production for the product to be produced, the animals shall remain in the quarantine area until such tests have been performed and the results obtained. Animals which do not meet the requirements shall not be admitted to the production area or allowed to contact production animals.

(c) All animals admitted to the premises of a licensed establishment shall be permanently identified either collectively or individually by the licensee with tags, marks, or other means acceptable to the Deputy Administrator.

(d) When an animal which has a disease is to be used to prepare a biological product for control of such disease, the animal shall be admitted directly to the processing facilities in which the product is to be prepared but shall not be permitted contact with other animals on the premises.

(e) The Deputy Administrator may authorize the maintenance of diagnostic facilities at the licensed establishment: *Provided,* That safeguards proposed by the licensee are adequate to prevent diseased or dead animals brought into such facilities from being a threat to biological products prepared in such establishment or to other animals on the premises used in the preparation of biological products.

§ 117.4 Test animals.

(a) All test animals shall be examined for clinical signs of illness, injury, or abnormal behavior prior to the start of a test and throughout the observation period specified in the test protocol.

(b) All animals used for test purposes shall be identified either collectively or individually in a manner conducive to an accurate interpretation of the results of the test.

(c) No test animals shall be given a biological product during the preconditioning period which would affect its eligibility according to the test requirements. No treatment, with a biological product or otherwise, shall be administered to a test animal during a test period which could interfere with a true evaluation of the biological product being tested.

§ 117.5 Segregation of animals.

Animals which have been infected with or exposed to a dangerous, infectious, contagious, or communicable disease shall be kept effectively segregated at a licensed establishment until such time as they are humanely destroyed or successfully treated and removed as healthy animals.

§ 117.6 Removal of animals.

Production animals or ex-test animals which are no longer useful at the licensed establishment may be removed from the premises of the licensed establishment; provided, such removal is accomplished in a manner as shall preclude the dissemination of disease and in accordance with the following conditions:

(a) Meat-producing animals which received a biological product containing inactivated microorganisms and adjuvants within 21 days shall not be removed; or

(b) Animals which received virulent microorganisms within 30 days shall not be removed; or

(c) Only animals that are in a healthy condition as determined by a veterinarian shall be removed, except as provided in paragraph (d) of this section.

(d) Other animals that are injured or otherwise unhealthy, except when affected with a communicable disease, may be removed for immediate slaughter to an abattoir operated in accordance with the Federal Meat Inspection

Act of March 4, 1907, 34 Stat. 1260, as amended by the Wholesome Meat Act of 1967, 81 Stat. 585 (21 U.S.C. sec. 601 et seq.): *Provided*, That such animals shall be properly marked for identification and the inspector in charge of slaughter operations is given due notice in advance.

(e) All animals on the premises shall be disposed of in accordance with the provisions of the regulations in this part and where specific provision is not made therefor shall be disposed of as required by the Deputy Administrator.

PART 122—ORGANISMS AND VECTORS

Sec.
122.1 Definitions.
122.2 Permits required.
122.3 Application for permits.
122.4 Suspension or revocation of permits.

AUTHORITY: Sec. 2, 32 Stat. 792, 37 Stat. 832-833; 21 U.S.C. 111, 151-158.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

§ 122.1 Definitions.

The following words, when used in the regulations in this Part 122, shall be construed, respectively, to mean:

(a) *Department*. The U.S. Department of Agriculture.

(b) *Secretary*. "Secretary" means the Secretary of Agriculture of the United States, or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

(c) *Veterinary Services*. The Veterinary Services unit of the Department.

(d) *Deputy Administrator*. The Deputy Administrator, Veterinary Services or any officer or employee of the Veterinary Services to whom authority has heretofore lawfully been delegated, or may hereafter lawfully be delegated, to act in his stead.

(e) *Organisms*. All cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals (including poultry).

(f) *Vectors*. All animals (including poultry) such as mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens, dogs, and the like, which have been treated or inoculated with organisms, or which are diseased or infected with any contagious, infectious, or communicable disease of animals or poultry or which have been exposed to any such disease.

(g) *Permittee*. A person who resides in the United States or operates a business establishment within the United States, to whom a permit to import or transport organisms or vectors has been issued under the regulations.

(h) *Person*. Any individual, firm, partnership, corporation, company, society, association, or other organized group of any of the foregoing, or any agent, officer, or employee of any thereof.

[31 FR 81, Jan. 5, 1966]

§ 122.2 Permits required.

No organisms or vectors shall be imported into the United States or transported from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia without a permit issued by the Secretary and in compliance with the terms thereof: *Provided*, That no permit shall be required under this section for importation of organisms for which an import permit has been issued pursuant to Part 102 of this subchapter or for transportation of organisms produced at establishments licensed under Part 102 of this subchapter. As a condition of issuance of permits under this section, the permittee shall agree in writing to observe the safeguards prescribed by the Deputy Administrator for public protection with respect to the particular importation or transportation.

(Approved by the Office of Management and Budget under control number 0579-0013)

[28 FR 7896, Aug. 2, 1963. Redesignated at 31 FR 81, Jan. 5, 1966 and amended at 48 FR 57473, Dec. 30, 1983]

§ 122.3 Application for permits.

The Secretary may issue, at his discretion, a permit as specified in § 122.2 when proper safeguards are set up as provided in § 122.2 to protect the public. Application for such a permit shall be made in advance of shipment, and each permit shall specify the name and address of the consignee, the true name and character of each of the organisms or vectors involved, and the use to which each will be put.

(Approved by the Office of Management and Budget under control number 0579-0015)

[23 FR 10065, Dec. 23, 1958. Redesignated at 31 FR 81, Jan. 5, 1966 and amended at 48 FR 57473, Dec. 30, 1983]

§ 122.4 Suspension or revocation of permits.

(a) Any permit for the importation or transportation of organisms or vectors issued under this part may be formally suspended or revoked after opportunity for hearing has been accorded the permittee, as provided in Part 123 of this subchapter, if the Secretary finds that the permittee has failed to observe the safeguards and instructions prescribed by the Deputy Administrator with respect to the particular importation or transportation or that such importation or transportation for any other reason may result in the introduction or dissemination from a foreign country into the United States, or from one State, Territory or the District of Columbia to another, of the contagion of any contagious, infectious or communicable disease of animals (including poultry).

(b) In cases of wilfulness or where the public health, interest or safety so requires, however, the Secretary may without hearing informally suspend such a permit upon the grounds set forth in paragraph (a) of this section, pending determination of formal proceedings under Part 123 of this subchapter for suspension or revocation of the permit.

[23 FR 10065, Dec. 23, 1958. Redesignated at 31 FR 81, Jan. 5, 1966]

PART 123—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE VIRUS-SERUM-TOXIN ACT

§ 123.1 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the Department of Agriculture promulgated in Subpart H of Part 1, Subtitle A, Title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings under the Virus-Serum-Toxin Act.

(Sec. 2, 32 Stat. 792, 37 Stat. 832-833 (21 U.S.C. 111, 151-158))

[42 FR 10960, Feb. 25, 1977]

SUBCHAPTER F—POULTRY IMPROVEMENT

PART 145—NATIONAL POULTRY IMPROVEMENT PLAN

Subpart A—General Provisions

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145.1 Definitions.
145.2 Administration.
145.3 Participation.
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145.5 Specific provisions for participating flocks.
145.6 Specific provisions for participating hatcheries.
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145.9 Terminology and classification; hatcheries and dealers.
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145.52 Participation.
145.53 Terminology and classification; flocks and products.
145.54 Terminology and classification; States.

AUTHORITY: 7 U.S.C. 429; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 36 FR 23112, Dec. 3, 1971, unless otherwise noted. Redesignated at 44 FR 61586, Oct. 26, 1979.

EDITORIAL NOTE: Nomenclature changes, see 44 FR 61586, Oct. 26, 1979.

Subpart A—General Provisions

§ 145.1 Definitions.

Words used in this part in the singular form shall be deemed to import the plural, and vice versa, as the case may demand. Except where the context otherwise requires, for the purposes of this part the following terms shall be construed, respectively, to mean:

(a) *Plan.* The provisions of the National Poultry Improvement Plan contained in this part.

(b) *Person.* A natural person, firm, or corporation.

(c) *Department.* The U.S. Department of Agriculture.

(d) *Service.* The Animal and Plant Health Inspection Service, Veterinary Services, of the Department.

(e) *State.* Any State, the District of Columbia, or Puerto Rico.

(f) *Official State Agency.* The State authority recognized by the Department to cooperate in the administration of the Plan.

(g) *State Inspector.* Any person employed or authorized under § 145.11(b) to perform functions under this part.

(h) *Authorized Agent.* Any person designated under § 145.11(a) to perform functions under this part.

(i) *Affiliated flockowner.* A flockowner who is participating in the Plan through an agreement with a participating hatchery.

(j) *Flock*—(1) *As applied to breeding.* All poultry of one kind of mating (breed and variety or combination of stocks) and of one classification on one farm;

(2) *As applied to disease control.* All of the poultry on one farm except that, at the discretion of the Official State Agency, any group of poultry which is segregated from another group and has been so segregated for a period of at least 21 days may be considered as a separate flock.

(k) *Hatchery.* Hatchery equipment on one premises operated or controlled by any person for the production of baby poultry.

(l) *Poultry.* Domesticated fowl, including chickens, turkeys, waterfowl, and game birds, except doves and pigeons, which are bred for the primary purpose of producing eggs or meat.

(m) *Domesticated.* Propagated and maintained under the control of a person.

(n) *Products.* Poultry breeding stock and hatching eggs, baby poultry, and started poultry.

(o) *Baby poultry.* Newly hatched poultry (chicks, poults, ducklings, goslings, keets, etc.) that have not been fed or watered.

(p) *Started poultry.* Young poultry (chicks, pullets, cockerels, capons, poults, ducklings, goslings, keets, etc.) that have been fed and watered and are less than 6 months of age.

(q) *Strain.* Poultry breeding stock bearing a given name produced by a breeder through at least five generations of closed flock breeding.

(r) *Stock.* A term used to identify the progeny of a specific breeding combination within a species of poultry. These breeding combinations may include pure strains, strain crosses, breed crosses, or combinations thereof.

(s) *Primary breeding flock.* A flock composed of one or more generations that is maintained for the purpose of establishing, continuing, or improving parent lines.

(t) *Multiplier breeding flock.* A flock that is intended for the production of hatching eggs used for the purpose of producing progeny for commercial egg or meat production or for other nonbreeding purposes.

(u) *Trade name or number.* A name or number compatible with State and Federal laws and regulations applied to a specified stock or product thereof.

(v) *Franchise breeder.* A breeder who normally sells products under a specific strain or trade name and who authorizes other hatcheries to produce and sell products under this same strain or trade name.

(w) *Franchise hatchery.* A hatchery which has been authorized by a franchise breeder to produce and sell products under the breeder's strain or trade name.

(x) *Pullorum disease or pullorum.* A disease of poultry caused by Salmonella pullorum.

(y) *Fowl typhoid or typhoid.* A disease of poultry caused by Salmonella gallinarum.

(z) *S. typhimurium infection or typhimurium.* A disease of poultry caused by Salmonella typhimurium or S. typhimurium var. copenhagen.

(aa) *Official supervision*—(1) *As applied to Plan programs.* The direction, inspection, and critical evaluation by the Official State Agency of compliance with the provisions of the Plan;

(2) *As applied to non-Plan but equivalent State poultry improvement programs.* The direction, inspection, and critical evaluation by an officer or agency of a State government, of compliance with a publicly announced State poultry improvement program.

(bb) *Authorized laboratory.* A laboratory designated by an Official State Agency, subject to review by the Service, to perform the blood testing and bacteriological examinations provided for in this part.

(cc) *Salmonella.* Any bacteria belonging to the genus Salmonella, including the arizona group.

(dd) Colon bacilli. For the purpose of this chapter, those organisms which are gram negative, non spore-forming bacilli, which ferment lactose with gas formation, and serve as an index of fecal contamination.

(ee) *Equivalent or equivalent requirements.* Requirements which are equal to the program, conditions, criteria, or classifications with which compared, as determined by the Official State Agency and with the concurrence of the Service.

(ff) *Sexual Maturity.* The average age at which a species of poultry is biologically capable of reproduction.

(gg) *Sanitize.* To treat with a product which is registered by the Environmental Protection Agency as germicidal, fungicidal, pseudomonocidal, or tuberculocidal, in accordance with the specifications for use as shown on the label of each product. The Official State Agency, with the concurrence of the Service, shall approve each product or procedure according to its specified usage.

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13706, May 24, 1973; 41 FR 14256, Apr. 2, 1976; 41 FR 48723, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 47 FR 21991, May 20, 1982; 49 FR 19802, May 10, 1984; 50 FR 19898, May 13, 1985]

§ 145.2 Administration.

(a) The Department cooperates through a Memorandum of Understanding with Official State Agencies in the administration of the Plan.

(b) The administrative procedures and decisions of the Official State Agency are subject to review by the Service. The Official State Agency shall carry out the administration of the Plan within the State according to the applicable provisions of the Plan and the Memorandum of Understanding.

(c) An Official State Agency may accept for participation an affiliated flock located in another State under a mutual understanding and agreement, in writing, between the two Official State Agencies regarding conditions of participation and supervision.

(d) The Official State Agency of any State may, except as limited by § 145.3(d), adopt regulations applicable to the administration of the Plan in such State further defining the provisions of the Plan or establishing higher standards compatible with the Plan.

(Approved by the Office of Management and Budget under control number 0579-0007)

[36 FR 23112, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 48 FR 57473, Dec. 30, 1983]

§ 145.3 Participation.

(a) Any person producing or dealing in products may participate in the Plan when he has demonstrated, to the satisfaction of the Official State Agency, that his facilities, personnel, and practices are adequate for carrying out the applicable provisions of the Plan, and has signed an agreement with the Official State Agency to comply with the general and the applicable specific provisions of the Plan and any regulations of the Official State Agency under § 145.2. Affiliated flockowners may participate without signing an agreement with the Official State Agency.

(b) Each participant shall comply with the Plan throughout the operating year of the Official State Agency, or until released by such Agency.

(c) A participant in any State shall participate with all of his poultry hatching egg supply flocks and hatchery operations within such State. He shall report to the Official State Agency on NPIP Form 3B or through other appropriate means each breeding flock before the birds reach 24 weeks of age. This report will include:

(1) Name and address of flockowner;
(2) Flock location and designation;
(3) Type: Primary or Multiplier;
(4) Breed, variety, strain, or trade name of stock;
(5) Source of males;
(6) Source of females;
(7) Number of birds in the flock; and
(8) Intended classification of flock.

(d) No person shall be compelled by the Official State Agency to qualify products for any of the other classifications described in § 145.10 as a condition of qualification for the U.S. Pullorum-Typhoid Clean classification.

(e) Participation in the Plan shall entitle the participant to use the Plan emblem reproduced below:

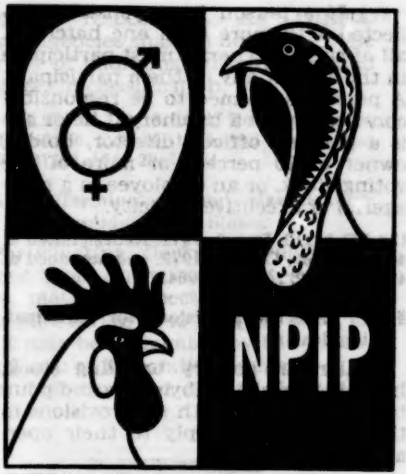


FIGURE 1.

(Approved by the Office of Management and Budget under control number 0579-0007)

[36 FR 23112, Dec. 3, 1971, as amended at 40 FR 1500, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979 and amended at 48 FR 57473, Dec. 30, 1983]

§ 145.4 General provisions for all participants.

(a) Records of purchases and sales and the identity of products handled shall be maintained in a manner satisfactory to the Official State Agency.

(b) Products, records of sales and purchase of products, and material used to advertise products shall be subject to inspection by the Official State Agency at any time.

(c) Advertising must be in accordance with the Plan, and applicable rules and regulations of the Official State Agency and the Federal Trade Commission. A participant advertising products as being of any official classification may include in his advertising reference to associated or franchised hatcheries only when such hatcheries produce the same kind of products of the same classification.

(d) Participants may not buy, sell, or receive for any purpose products from nonparticipants, *Provided*, That with the permission of the Official State Agency and approval of the Service, other products may be bought or received for use in breeding flocks or for experimental purposes.

(e) Each participant shall be assigned a permanent approval number by the Service. This number, prefaced by the numerical code of the State, will be the official approval number of the participant and may be used on each certificate, invoice, shipping label, or other document used by the participant in the sale of his products. Each Official State Agency which requires an approval or permit number for out-of-State participants to ship into its State should honor this number. The approval number shall be withdrawn when the participant no longer qualifies for participation in the Plan.

(Approved by the Office of Management and Budget under control number 0579-0057)

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13706, May 24, 1973; 41 FR 48723, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, as amended at 47 FR 21991, May 20, 1982; 48 FR 57473, Dec. 30, 1983]

§ 145.5 Specific provisions for participating flocks.

(a) Poultry equipment, and poultry houses and the land in the immediate vicinity thereof, shall be kept in sanitary condition as recommended in §§ 147.21 and 147.22 (a) and (e) of this chapter. The participating flock, its eggs, and all equipment used in connection with the flock shall be separated from nonparticipating flocks, in a manner acceptable to the Official State Agency.

(b) All flocks shall consist of healthy, normal individuals characteristic of the breed, variety, cross, or other combination which they are stated to represent.

(c) A flock shall be deemed to be a participating flock at any time only if it has qualified for the U.S. Pullorum-Typhoid Clean classification, as prescribed in Subparts B, C, D, or E of this part.

(d) Each bird shall be identified with a sealed and numbered band obtained through or approved by the Official State Agency: *Provided*, That exception may be made at the discretion of the Official State Agency.

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13706, May 24, 1973. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 145.6 Specific provisions for participating hatcheries.

(a) Hatcheries, including brooder rooms, shall be kept in sanitary condition, acceptable to the Official State Agency. The procedures outlined in §§ 147.22 through 147.25 of this chapter shall be considered as a guide in determining compliance with this provision. The minimum requirements with respect to sanitation shall include the following:

(1) Incubator walls, floors, and trays shall be kept free from broken eggs and eggshells.

(2) Tops of incubators and hatchers shall be kept clean (not used for storage).

(3) Entire hatchery, including sales room, shall be kept in a neat, orderly condition and free from accumulated dust.

(4) Hatchery residue, such as eggshells, infertile eggs, and dead germs, shall be disposed of promptly and in a manner satisfactory to the Official State Agency.

(5) Hatchers and hatching trays shall be cleaned and fumigated or disinfected after each hatch, preferably using the procedures outlined in §§ 147.24(b) and 147.25(e) of this chapter. While not mandatory for participation, all eggs set should be fumigated as described in § 147.25 or otherwise sanitized.

(b) A hatchery which keeps started poultry must keep such poultry separated from the incubator room in a manner satisfactory to the Official State Agency.

(c) All baby and started poultry offered for sale under Plan terminology shall be normal and typical of the breed, variety, cross, or other combination represented.

(d) Eggs incubated shall be sound in shell, typical for the breed, variety, strain, or cross thereof and reasonably uniform in shape. Hatching eggs shall be trayed and the baby poultry boxed with a view to uniformity of size.

(e) If a person is responsibly connected with more than one hatchery, all of such hatcheries must participate in the Plan if any of them participate. A person is deemed to be responsibly connected with a hatchery if he or she is a partner, officer, director, holder, owner of 10 percent or more of the voting stock, or an employee in a managerial or executive capacity.

[36 FR 23112, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19802, May 10, 1984]

§ 145.7 Specific provisions for participating dealers.

Dealers in poultry breeding stock, hatching eggs, or baby or started poultry shall comply with all provisions in this part which apply to their operations.

§ 145.8 Terminology and classification; general.

(a) The official classification terms defined in §§ 145.9 and 145.10 and the various designs illustrative of the official classifications reproduced in § 145.10 may be used only by participants and to describe products that have met all the specific requirements of such classifications.

(b) Products produced under the Plan shall lose their identity under Plan terminology when they are purchased for resale by or consigned to nonparticipants.

(c) Participating flocks, their eggs, and the baby and started poultry produced from them may be designated by their strain or trade name. When a breeder's trade name or strain designation is used, the participant shall be able by records to substantiate that the products so designated are from flocks that are composed of either birds hatched from eggs produced under the direct supervision of the breeder of such strain, or stock multiplied by persons designated and so reported by the breeder to each Official State Agency concerned.

§ 145.9 Terminology and classification; hatcheries and dealers.

Participating hatcheries and dealers shall be designated as "National Plan Hatchery" and "National Plan

Dealer", respectively. All Official State Agencies shall be notified by the Service of additions, withdrawals, and changes in classification.

[36 FR 23112, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 47 FR 21991, May 20, 1982]

§ 145.10 Terminology and classification; flocks, products, and States.

Participating flocks, products produced from them, and States which have met the respective requirements specified in Part 145 Subpart B, C, D, or E may be designated by the following terms or illustrative designs:

(a) *U.S. Approved.* (See § 145.53(a).)

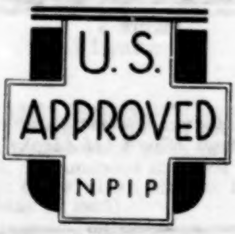

U.S.
APPROVED
NPIP

FIGURE 2

(b) *U.S. Pullorum-Typhoid Clean.* (See § 145.23(b), § 145.33(b), § 145.43(b), and § 145.53(b).)

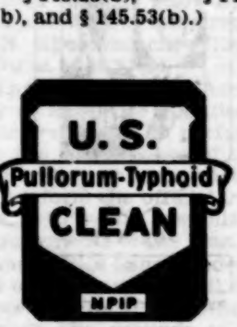

U.S.
Pullorum-Typhoid
CLEAN
NPIP

FIGURE 3

(c) *U.S. M. Gallisepticum Clean.* (See § 145.23(c), § 145.23(f), § 145.33(c), § 145.33(f), § 145.43(c), and § 145.53(c).)

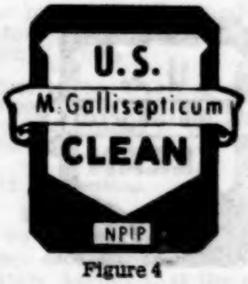

U.S.
M. Gallisepticum
CLEAN
NPIP

Figure 4

(d) *U.S. Sanitation Monitored.* (See § 145.23(d) and § 145.33(d).)

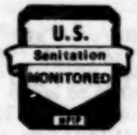

U.S.
Sanitation
MONITORED
NPIP

FIGURE 5

(e) *U.S. M. Synoviae Clean.* (See § 145.23(e), § 145.23(g), § 145.33(e), § 145.33(g), and § 145.43(e)).

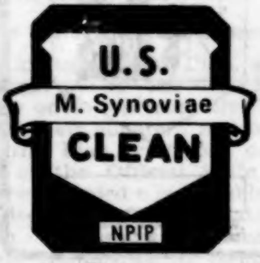

U.S.
M. Synoviae
CLEAN
NPIP

Figure 6

(f) *U.S. M. Meleagridis Clean*—(See § 145.43(d)).

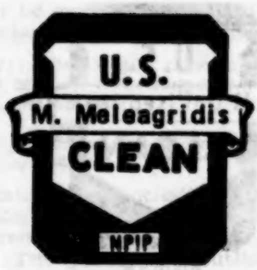

U.S.
M. Meleagridis
CLEAN
NPIP

Figure 7

(g) *U.S. Pullorum-Typhoid Clean State*—(See § 145.24(a), § 145.34(a), § 145.44(a), and § 145.54(a).)

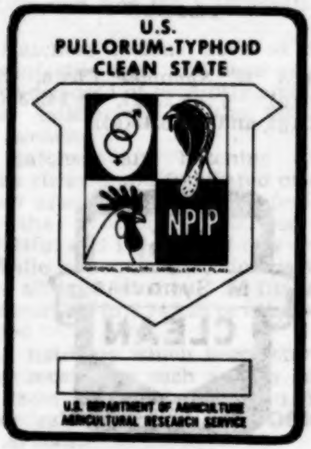

U.S.
PULLORUM-TYPHOID
CLEAN STATE
NPIP
U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE

Figure 8

(h) *U.S. Pullorum-Typhoid Clean State, Turkeys*—(See § 145.44(b).)

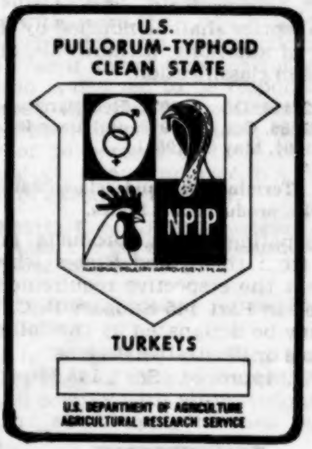
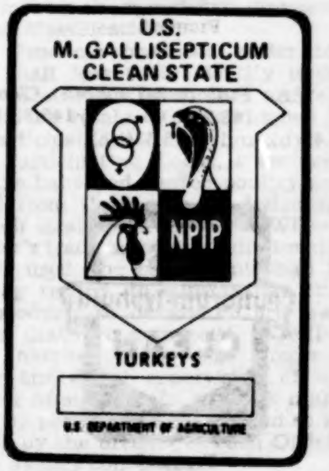

U.S.
PULLORUM-TYPHOID
CLEAN STATE
NPIP
TURKEYS
U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE

Figure 9

(i) *Mycoplasma Gallisepticum Clean State, Turkeys.* (See § 145.44(c).)


U.S.
M. GALLISEPTICUM
CLEAN STATE
NPIP
TURKEYS
U.S. DEPARTMENT OF AGRICULTURE

(j) *U.S. M. Gallisepticum Clean State, Meat-Type Chickens.* (See § 145.34(b).)

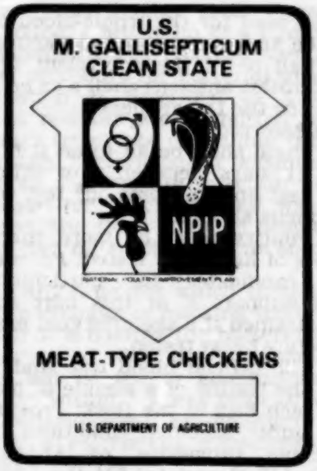

U.S.
M. GALLISEPTICUM
CLEAN STATE
NPIP
NATIONAL POULTRY IMPROVEMENT PLAN
MEAT-TYPE CHICKENS
U.S. DEPARTMENT OF AGRICULTURE

Figure 11

[38 FR 13706, May 24, 1973, as amended at 40 FR 1500, Jan. 8, 1975; 41 FR 48723, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 45 FR 10315, Feb. 15, 1980; 47 FR 21991, May 20, 1982; 50 FR 19898, May 13, 1985]

§ 145.11 Supervision.

(a) The Official State Agency may designate qualified persons as Authorized Agents to do the sample collecting and blood testing provided for in § 145.14 and the selecting required for the U.S. Approved classification provided for in § 145.53(a).

(b) The Official State Agency shall employ or authorize qualified persons as State Inspectors to perform or supervise the performance of the selecting and testing of participating flocks, and to perform the official inspections necessary to verify compliance with the requirements of the Plan.

(c) Authorities issued under the provisions of this section shall be subject to cancellation by the official State agency on the grounds of incompetence or failure to comply with the provisions of the Plan or regulations of the official State agency. Such actions shall not be taken until a thorough investigation has been made by the official State agency and the authorized person has been given notice of the proposed action and the basis therefor and an opportunity to present his views.

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13706, May 24, 1973; 41 FR 48723, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 145.12 Inspections.

(a) Each participating hatchery shall be inspected a sufficient number of times each year to satisfy the Official State Agency that the operations of the hatchery are in compliance with the provisions of the Plan.

(b) Each year at least 15 percent of the independent flocks and the affiliated flocks of each hatchery shall be inspected by a State Inspector. Each inspection shall include the examination of a sufficient number of males and females and, in flocks qualified for participation by the whole-blood test, the blood testing of a sufficient number of birds to determine whether the work of the Authorized Agent was satisfactory and that the flock is qualified for participation. The State Inspector shall also determine whether or not the flock and premises are in compliance with the provisions in § 145.5(a) and (b).

[36 FR 23112, Dec. 3, 1971, as amended at 40 FR 1501, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 145.13 Debarment from participation.

Participants in the Plan, who after investigation by the Official State Agency or its representative, are notified of their apparent noncompliance with the Plan provisions or regulations of the Official State Agency, shall be afforded a reasonable time, as specified by the Official State Agency, within which to demonstrate or achieve compliance. If compliance is not demonstrated or achieved within the specified time, the Official State Agency may debar the participant from further participation in the Plan for such period, or indefinitely, as the Agency may deem appropriate. The debarred participant shall be afforded notice of the bases for the debarment and opportunity to present his views with respect to the debarment in accordance with procedures adopted by the Official State Agency. The Official State Agency shall thereupon decide whether the debarment order shall continue in effect. Such decision shall be final unless the debarred participant, within 30 days after the issuance of the debarment order, requests the Administrator to determine the eligibility of the debarred participant for participation in the Plan. In such event the Administrator shall determine the matter de novo in accordance with §§ 50.21 through 50.28-14 and §§ 50.30 through 50.33 of the rules of practice in 7 CFR Part 50, which are hereby made applicable to proceedings before the Administrator under this section. The definitions in 7 CFR 50.2(e),(g),(h), and (l) and the following definitions shall apply with respect to terms used in such rules of practice:

(a) "Administrator" means the Administrator, Animal and Plant Health Inspection Service of the U.S. Department of Agriculture or any officer or employee to whom authority has heretofore been delegated or to whom authority may hereafter be delegated to act in his stead.

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 3038, Feb. 1, 1973. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 47 FR 21991, May 20, 1982]

§ 145.14 Blood testing.

Blood samples for official tests shall be drawn by an Authorized Agent or State Inspector and tested by an authorized laboratory, except that the stained-antigen, rapid whole-blood test for pullorum-typhoid may be conducted by an Authorized Agent or State Inspector. For those programs where a sample of the poultry may be tested in lieu of the entire flock, the poultry tested shall be a representative sample drawn from all pens or units of the flock.

(a) *For Salmonella.* (1) The official blood tests for pullorum-typhoid shall be the standard tube agglutination test, the microagglutination test, or the rapid serum test for all classes of poultry or the stained antigen, rapid whole-blood test for all classes of poultry except turkeys. The recommended procedures for conducting such tests are described in §§ 147.1, 147.2, 147.3, and 147.5 of this chapter. Each lot of antigen used for the whole-blood test shall be approved by the Department and shall be of the polyvalent type. All microtest antigens shall also be approved by the Department.

(2) [Reserved]

(3) There shall be an interval of at least 21 days between any official blood test and any previous test with Salmonella antigen.

(4) Poultry must be more than 4 months of age when tested: *Provided,* That candidates for participation under Subpart E of this part shall have attained the age of sexual maturity before being tested.

(5) The official blood test shall include the testing of a sample of blood from each bird in the flock: *Provided,* That under specified conditions (see applicable provisions of §§ 145.23, 145.33, 145.43 and 145.53) the testing of a portion or sample of the birds may be used in lieu of testing each bird. When reactors are found in any flock, or S. pullorum or S. gallinarum isolations are made from baby poultry or fluff samples, the flock may qualify for participation with two consecutive official negative tests. Qualification of this flock, or any other flock on the same premises during the next 12 months, shall be based on the testing of all birds. Such testing shall be conducted by or directly supervised by a State Inspector.

(6) All domesticated fowl, except waterfowl, on the farm of the participant shall either be properly tested to meet the same standards as the participating flock or these birds and their eggs shall be separated from the participating flock and its eggs.

(7) All tests with Salmonella antigens of flocks participating in or candidates for participation in the Plan shall be reported to the Official State Agency within 10 days following the completion of such tests. All reactors shall be considered in determining the classification of the flock.

(8) Reactors shall be submitted to a laboratory for autopsy and bacteriological examination. All reactors in a flock if there are 4 or less reactors shall be submitted to a laboratory designated by the Official State Agency for bacteriological examination, as described in § 147.11 of this chapter: *Pro-*

vided, That if more than 4 reactors are found, a minimum of 4 birds shall be submitted. The recommended minimum procedure for bacteriological examination is described in § 147.11. When reactors are submitted within 10 days from date of reading the test and the bacteriological examination fails to demonstrate infection of the serotype for which the test was conducted, the flock shall be deemed to have had no reactors to the specified test.

(9) Any drug, for which there is scientific evidence of masking the test reaction or hindering the bacteriological recovery of Salmonella organisms, shall not be fed or administered to poultry within 3 weeks prior to a test or bacteriological examination upon which a Salmonella classification is based.

(10) When suitable evidence, as determined by the Official State Agency or the State Animal Disease Control Official, indicates that baby or started poultry produced by participating hatcheries are infected with organisms for which the parent flock received an official control classification and this evidence indicates that the infection was transmitted from the parent flock, the Official State Agency may, at its discretion, require additional testing of the flock involved. If infection is found in the parent flock, its classification shall be suspended until the flock is requalified under the requirements for the classification. Furthermore, the Official State Agency may require that the hatching eggs from such flocks be removed from the incubator and destroyed prior to hatching. When Salmonella organisms are isolated from a specimen which originated in a participating hatchery, the Official State Agency shall attempt to locate the source of the infection. The results of the investigation and the action taken to eliminate the infection shall be reported by the Official State Agency to the Service.

(b) *For M. gallisepticum and M. synoviae:* (1) The official blood tests for *M. gallisepticum* and *M. synoviae* shall be the serum plate agglutination test, the tube agglutination test, the hemagglutination inhibition (HI) test, the microhemagglutination inhibition test, the enzyme-labeled immunosorbent assay (ELISA) test [1] or a combination of two or more of these tests. The HI test, the microhemagglutination inhibition test, and the ELISA test shall be used to confirm the positive results of other serological tests. HI titers of 1:40 or less may be interpreted as equivocal, and final judgment may be based on further samplings and/or culture of reactors.

(2) The tests shall be conducted using M. gallisepticum or M. synoviae antigens approved by the Department or the Official State Agency and shall be performed in accordance with the recommendations of the producer of the antigen.

(3) When reactors to the test for which the flock was tested are submitted to a laboratory as prescribed by the Official State Agency, the criteria found in § 147.6 shall be used in determining the final status of the flock.

(4) Any drug, for which there is scientific evidence of masking the test reaction or hindering the bacteriological recovery of mycoplasma organisms, shall not be fed or administered to poultry within three weeks prior to a test or bacteriological examination upon which a Mycoplasma classification is based.

(c) *For M. meleagridis.* The official blood tests for *M. meleagridis* are specified in § 145.43(d)(2).

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[1] Procedures for the enzyme-labeled immunosorbent assay (ELISA) test are set forth in the following publications:

A.A. Ansari, R.F. Taylor, T.S. Chang, "Application of Enzyme-Linked Immunosorbent Assay for Detecting Antibody to Mycoplasma gallisepticum Infections in Poultry," *Avian Diseases,* Vol. 27, No. 1, pp. 21-35, January-March 1983; and

H.M. Opitz, J.B. Duplessis, and M.J. Cyr, "Indirect Micro-Enzyme-Linked Immunosorbent Assay for the Detection of Antibodies to Mycoplasma synoviae and M. gallisepticum," *Avian Diseases,* Vol. 27, No. 3, pp. 773-786, July-September 1983; and

H.B. Ortmayer and R. Yamamoto, "Mycoplasma Meleagridis Antibody Detection by Enzyme-Linked Immunosorbent Assay (ELISA)," *Proceedings, 30th Western Poultry Disease Conference,* pp. 63-66, March 1981.

(Approved by the Office of Management and Budget under control number 0579-0007)

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13706, May 24, 1973; 40 FR 1501, Jan. 8, 1975; 41 FR 48723, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 45 FR 10315, Feb. 15, 1980; 47 FR 21991, May 20, 1982; 48 FR 57473, Dec. 30, 1983; 50 FR 19898, May 13, 1985]

Subpart B—Special Provisions for Egg Type Chicken Breeding Flocks and Products

§ 145.21 Definitions.

Except where the context otherwise requires, for the purposes of this subpart the following terms shall be construed, respectively, to mean:

(a) *Egg type chicken breeding flocks.* Flocks that are composed of stock that has been developed for egg production and are maintained for the principal purpose of producing chicks for the ultimate production of eggs for human consumption.

(b) *Chicks.* Newly hatched chickens which have not been fed or watered.

(c) *Started chickens.* Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13707, May 24, 1973; 41 FR 48723, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 145.22 Participation.

Participating flocks of egg type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of Subpart A of this part and the special provisions of this Subpart B.

(a) The minimum weight of hatching eggs sold shall be $1\frac{11}{12}$ ounces each, except as otherwise specified by the purchaser of the eggs.

(b) Mediterranean breed eggs shall be reasonably free from tints.

(c) Started chickens shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in § 145.5(a).

(d) Hatching eggs produced by primary breeding flocks shall be fumigated as described in § 147.25 or otherwise sanitized.

[36 FR 23112, Dec. 3, 1971, as amended at 40 FR 1501, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19802, May 10, 1984]

§ 145.23 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in § 145.10:

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the official State agency under the criteria in one of the following paragraphs (b)(1) through (5) of this section: *Provided,* That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be at the discretion of the official State agency with the concurrence of the Service. (See § 145.14 relating to the official blood test where applicable.)

(1) It has been officially blood tested with no reactors.

(2) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, and meets the following specifications as determined by the Official State Agency and the Service:

(i) The flock is located in a State where all persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum or S. gallinarum is isolated;

(ii) The flock is composed entirely of birds that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision; and

(iii) A sample comprised of at least 25 percent of the birds in the flock has been officially blood tested with no reactors, or its progeny has been subjected to an approved 10-day chick mortality bacteriological examination monitoring program and bacteriological examination of a sample of down shed by chicks in the hatcher from selected hatches as prescribed by the Official State Agency: *Provided*, That when the blood testing procedure is used, the percentage of the flock included in the sample may be reduced by 5 percentage points following each year in which there is no evidence of infection on the premises until the required percentage is reduced to zero: *And provided further*, That the sample tested for the qualification of a flock under this subparagraph shall include at least 500 birds the first year, 400 the second year, 300 the third year, 200 the fourth year, and 100 the fifth year.

(3) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision, and is located in a State in which it has been determined by the Service that: (i) All hatcheries, except turkey hatcheries, within the State are qualified as "National Plan Hatcheries" or have met equivalent requirements for pullorum-typhoid control under official supervision;

(ii) All hatchery supply flocks, except turkey flocks, within the State, are qualified as U.S. Pullorum-Typhoid Clean or have met equivalent requirements for pullorum-typhoid control under official supervision: *Provided*, That if other domesticated fowl, except waterfowl, are maintained on the same premises as the participating flock, freedom from pullorum-typhoid infection shall be demonstrated by an official blood test of each of these fowl;

(iii) All shipments of products other than U.S. Pullorum-Typhoid Clean, or equivalent, into the State are prohibited;

(iv) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum or S. gallinarum is isolated;

(v) All reports of S. pullorum or S. gallinarum isolations from poultry are promptly followed by an investigation by the Official State Agency to determine the origin of the infection;

(vi) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested, following the procedure for reacting flocks as contained in § 145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

(vii) All poultry, including exhibition, exotic, and game birds, but excluding waterfowl, going to public exhibition shall come from U.S. Pullorum-Typhoid Clean or equivalent flocks, or have had a negative pullorum-typhoid test within 90 days of going to public exhibition;

(viii) Discontinuation of any of the conditions or procedures described in paragraphs (b)(3) (i), (ii), (iii), (iv), (v), (vi), and (vii) of this section, or the occurrence of repeated outbreaks of pullorum or typhoid in poultry breeding flocks, other than turkey flocks, within or originating within the State shall be grounds for the Service to revoke its determination that such conditions and procedures have been met or complied with. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity to present its views.

(4) It is a multiplier breeding flock located in a State which has been determined by the Service to be in compliance with the provisions of (b)(3) of this section, and in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks, other than turkey, waterfowl, exhibition poultry, and game bird supply flocks, within the State during the preceding 12 months.

(5) It is a primary breeding flock located in a State determined to be in compliance with the provisions of paragraph (b)(4) of this section, and in which a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with no reactors: *Provided*, That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of blood testing.

(c) *U.S. M. Gallisepticum Clean.* (1) A flock maintained in compliance with the provisions of § 147.26 of this chapter and in which freedom from M. gallisepticum has been demonstrated under the criteria specified in paragraph (c)(1) (i) or (ii) of this section.

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for *M. gallisepticum* as provided in § 145.14(b) when more than 4 months of age: *Provided*, That to retain this classification, a minimum of 150 birds shall be tested at intervals of not more than 90 days: *And provided further*, That a sample comprised of less than 150 birds may be tested at any one time, with the approval of the Official State Agency and the concurrence of the Service, provided that a minimum of 150 birds is tested within each 90-day period; or

(ii) It is a multiplier breeding flock which originated as U.S. M. Gallisepticum Clean chicks from primary breeding flocks and from which a sample comprised of a minimum of 150 birds per flock has been tested for *M. gallisepticum* as provided in § 145.14(b) when more than 4 months of age: *Provided*, That to retain this classification, the flock shall be subjected to one of the following procedures:

(A) At intervals of not more than 90 days, a sample of 75 birds, with a minimum of 30 birds per pen, whichever is greater, shall be tested; or

(B) At intervals of not more than 30 days, a sample of 25 cull chicks produced from the flock shall be subjected to laboratory procedures acceptable to the Official State Agency and approved by the Service, for the detection and recovery of M. gallisepticum; or

(C) At intervals of not more than 30 days, egg yolk testing shall be conducted in accordance with § 147.8.

(2) A participant handling U.S. M. Gallisepticum Clean products shall keep these products separate from other products in a manner satisfactory to the Official State Agency: *Provided*, That U.S. M. Gallisepticum Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (c)(1)(i) of this section are set.

(3) U.S. M. Gallisepticum Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in § 147.24(a) of this chapter.

(d) *U.S. Sanitation Monitored.* This program is intended to be the basis from which the breeding-hatching industry may conduct a program for the prevention and control of Salmonellosis. It is intended to reduce the incidence of Salmonella organisms in hatching eggs and chicks through an effective and practical sanitation program at the breeder farm and in the hatchery. This will afford other segments of the poultry industry an opportunity to reduce the incidence of Salmonella in their products.

(1) A flock and the hatching eggs and chicks produced from it which have met the following requirements as determined by the Official State Agency:

(i) The flock shall originate from a source where sanitation and management practices, as outlined in § 145.23(d)(1) of this paragraph, are conducted;

(ii) The flock is maintained in compliance with §§ 147.21, 147.24(a), and 147.26 of this chapter;

(iii) All feed should be pelletized and/or crumbled in mills operated at 190° F. or above in facilities for recontamination control;

(iv) Feed shall be stored and transported in such a manner as to prevent possible contamination;

(v) Hatching eggs are collected at least four times a day and are handled as described in § 147.22 and are fumigated on the farm as described in § 147.25(a) or otherwise sanitized.

(vi) Chicks are hatched in a hatchery meeting the requirements of §§ 147.23 and 147.24(b) and are in compliance with § 147.25(b) of this chapter.

(2) The Official State Agency may use the procedures described in § 147.14 of this chapter to monitor the effectiveness of the sanitation practices.

(3) In order for a hatchery to sell products of this classification, all products handled shall meet the requirements of the classification.

(4) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.

(e) *U.S.M. Synoviae Clean.* (1) A flock maintained in compliance with the provisions of § 147.26 and in which freedom from M. synoviae has been demonstrated under the criteria specified in paragraph (e)(1) (i) or (ii) of this section.

(i) It is a flock in which a minimum of 300 birds has been tested for *M. synoviae* as provided in § 145.14(b) when more than 4 months of age: *Provided,* That to retain this classification, a sample of at least 150 birds shall be tested at intervals of not more than 90 days: *And provided further,* That a sample comprised of less than 150 birds may be tested at any one time, with the approval of the Official State Agency and the concurrence of the Service, provided that a minimum of 150 birds is tested within each 90-day period; or

(ii) It is a multiplier breeding flock which originated as U.S. M. Synoviae Clean chicks from primary breeding flocks and from which a sample comprised of a minimum of 75 birds has been tested for *M. synoviae* as provided in § 145.14(b) when more than 4 months of age: *Provided,* That to retain this classification, the flock shall be subjected to one of the following procedures:

(*a*) At intervals of not more than 90 days, a sample of 50 birds shall be tested: *Provided,* That a sample of less than 50 birds may be tested at any one time, provided that a minimum of 30 birds per flock with a minimum of 15 birds per pen, whichever is greater, is tested each time and a total of at least 50 birds is tested within each 90-day period; or

(*b*) At intervals of not more than 30 days, egg yolk testing shall be conducted in accordance with § 147.8.

(2) A participant handling U.S. M. Synoviae Clean products shall keep these products separate from other products in a manner satisfactory to the Official State Agency: *Provided,* That U.S. M. Synoviae Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (e)(1) (i) or (ii) of this section are set.

(3) U.S. M. Synoviae Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in § 147.24(a).

(f) *U.S. M. Gallisepticum Clean Started Poultry.* (1) A flock which originated from U.S. M. Gallisepticum Clean breeding flocks and was hatched in a hatchery approved by the Official State Agency for the production of U.S. *M. Gallisepticum* Clean chicks.

(2) All other poultry on the premises of the candidate flock must originate from U.S. M. Gallisepticum Clean sources.

(3) The flock is maintained in compliance with the provisions of § 147.26.

(4) The flock's freedom from *M. Gallisepticum* is demonstrated by a negative blood test, as provided in § 145.14(b), of a sample of 75 birds, with a minimum of 50 birds per poultry house, between 15–20 days prior to the flock being moved to laying quarters.

(5) Started poultry shall be delivered to and from the farm premises in crates and vehicles which have been cleaned and disinfected as described in § 145.24(a) of this chapter.

(g) *U.S. M. Synoviae Clean Started Poultry.* (1) A flock which originated from U.S. M. Synoviae Clean breeding flocks and was hatched in a hatchery approved by the Official State Agency for production of U.S. M. Synoviae Clean chicks.

(2) All other poultry on the premises of the candidate flock must originate from U.S. M. Synoviae Clean sources.

(3) The flock is maintained in compliance with the provisions of § 147.26.

(4) The flocks's freedom from *M. synoviae* is demonstrated by a negative blood test, as provided in § 145.14(b), of a sample of 75 birds, with a minimum of 50 birds per poultry house, between 15-20 days prior to the flock being moved to laying quarters.

(5) Started poultry shall be delivered to and from the farm premises in crates and vehicles which have been cleaned and disinfected as described in § 147.24(a) of this chapter.

(Approved by the Office of Management and Budget under control number 0579-0007)

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13707, May 24, 1973; 40 FR 1501, Jan. 8, 1975; 41 FR 48723, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 45 FR 10315, Feb. 15, 1980; 47 FR 21992, May 20, 1982; 48 FR 57473, Dec. 30, 1983; 49 FR 19802, May 10, 1984; 50 FR 19899, May 13, 1985]

§ 145.24 Terminology and classification; States.

(a) *U.S. Pullorum-Typhoid Clean State.* (1) A State will be declared a U.S. Pullorum-Typhoid Clean State when it has been determined by the Service that:

(i) The State is in compliance with the provisions contained in § 145.23(b)(3) (i) through (vii), § 145.33(b)(3) (i) through (vii), § 145.43(b)(3) (i) through (vi), and § 145.53(b)(3) (i) through (vii).

(ii) No pullorum disease or fowl typhoid is known to exist nor to have existed in hatchery supply flocks within the State during the preceding 12 months: *Provided,* That pullorum disease or fowl typhoid found in waterfowl, exhibition poultry, and game bird breeding flocks will not prevent a State, which is otherwise eligible, from qualifying for a period of two years.

(2) Discontinuation of any of the conditions described in paragraph (a)(1)(i) of this section, or repeated outbreaks of pullorum or typhoid occur in hatchery supply flocks described in paragraph (a)(1)(ii) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination that the State is entitled to this classification. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity for a hearing.

[40 FR 1502, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979]

Subpart C—Special Provisions for Meat Type Chicken Breeding Flocks and Products

§ 145.31 Definitions.

Except where the context otherwise requires, for the purposes of this subpart the following terms shall be construed, respectively, to mean:

(a) *Meat type chicken breeding flocks.* Flocks that are composed of stock that has been developed for meat production and are maintained for the principal purpose of producing chicks for the ultimate production of meat.

(b) *Chicks.* Newly hatched chickens which have not been fed or watered.

(c) *Started chickens.* Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.

[36 FR 23112, Dec. 3, 1971, as amended at 41 FR 48724, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 145.32 Participation.

Participating flocks of meat type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of Subpart A of this part and the special provisions of this Subpart C.

(a) The minimum weight of hatching eggs sold shall be $1\frac{19}{12}$ ounces each, except as otherwise specified by the purchaser of the eggs.

(b) Started chickens shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in § 145.5(a).

(c) Hatching eggs produced by primary breeding flocks shall be fumigated as described in § 147.25 or otherwise sanitized.

[36 FR 23112, Dec. 3, 1971, as amended at 40 FR 1502, Jan. 8, 1975; 41 FR 48724, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19802, May 10, 1984]

§ 145.33 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in § 145.10:

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the official State agency under the criteria in one of paragraphs (b) (1) through (5) of this section: *Provided,* That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be at the discretion of the official State agency with the concurrence of the Service. (See § 145.14 relating to the official blood test where applicable.)

(1) It has been officially blood tested with no reactors.

(2) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, and meets the following specifications as determined by the Official State Agency and the Service:

(i) The flock is located in a State where all persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum or S. gallinarum is isolated;

(ii) The flock is composed entirely of birds that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision; and

(iii) A sample comprised of at least 25 percent of the birds in the flock has been officially blood tested with no reactors, or its progeny has been subjected to an approved 10-day chick mortality bacteriological examination monitoring program and bacteriological examination of a sample of down shed by chicks in the hatcher from selected hatches as prescribed by the Official State Agency: *Provided,* That when the blood testing procedure is used, the percentage of the flock included in the sample may be reduced by 5 percentage points following each year in which there is no evidence of infection on the premises until the required percentage is reduced to zero: *And provided further,* That the sample tested for the qualification of a flock under this subparagraph shall include at least 500 birds the first year, 400 the second year, 300 the third year, 200 the fourth year, and 100 the fifth year.

(3) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision, and is located in a State in which it has been determined by the Service that:

(i) All hatcheries, except turkey hatcheries, within the State are qualified as "National Plan Hatcheries" or have met equivalent requirements for pullorum-typhoid control under official supervision;

(ii) All hatchery supply flocks, except turkey flocks, within the State, are qualified as U.S. Pullorum-Typhoid Clean or have met equivalent requirements for pullorum-typhoid control under official supervision: *Provided,* That if other domesticated fowl, except waterfowl, are maintained on the same premises as the participating flock, freedom from pullorum-typhoid infection shall be demonstrated by an official blood test of each of these fowl;

(iii) All shipments of products other than U.S. Pullorum-Typhoid Clean, or equivalent, into the State are prohibited;

(iv) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum or S. gallinarum is isolated;

(v) All reports of S. pullorum or S. gallinarum isolations from poultry are promptly followed by an investigation by the Official State Agency to determine the origin of the infection;

(vi) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested following the procedure for reacting flocks as contained in § 145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

(vii) All poultry, including exhibition, exotic, and game birds, but excluding waterfowl, going to public exhibition shall come from U.S. Pullorum-Typhoid Clean or equivalent flocks, or have had a negative pullorum-typhoid test within 90 days of going to public exhibition;

(viii) Discontinuation of any of the conditions or procedures described in paragraphs (b)(3) (i), (ii), (iii), (iv), (v), (vi), and (vii) of this section, or the occurrence of repeated outbreaks of pullorum or typhoid in poultry breeding flocks, other than turkey flocks, within or originating within the State shall be grounds for the Service to revoke its determination that such conditions and procedures have been met or complied with. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity to present its views.

(4) It is a multiplier breeding flock located in a State which has been determined by the Service to be in compliance with the provisions of paragraph (b)(3) of this section, and in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks, other than turkey, waterfowl, exhibition poultry, and game bird supply flocks, within the State during the preceding 12 months.

(5) It is a primary breeding flock located in a State determined to be in compliance with the provisions of paragraph (b)(4) of this section, and in which a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with no reactors: *Provided,* That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of blood testing.

(c) *U.S. M. Gallisepticum Clean.* (1) A flock maintained in compliance with the provisions of § 147.26 of this chapter and in which freedom from M. gallisepticum has been demonstrated under the criteria specified in paragraph (c)(1) (i) or (ii) of this section.

(i) It is a flock in which all birds or a simple of at least 300 birds has been tested for *M. gallisepticum* as provided in § 145.14(b) when more than 4 months of age: *Provided,* That to retain this classification, a minimum of 150 birds shall be tested at intervals of not more than 90 days: *And provided further,* That a sample comprised of less than 150 birds may be tested at any one time, with the approval of the Official State Agency and the concurrence of the Service, provided that a minimum of 150 birds is tested within each 90-day period; or

(ii) It is a multiplier breeding flock which originated as U.S. M. Gallisepticum Clean chicks from primary breeding flocks and from which a sample comprised of a minimum of 150 birds per flock has been tested for *M. gallisepticum* as provided in §145.14(b) when more than 4 months of age: *Provided,* That to retain this classification, the flock shall be subjected to one of the following procedures:

(A) At intervals of not more than 90 days, a sample of 75 birds, with a minimum of 30 birds per pen, whichever is greater shall be tested; or

(B) At intervals of not more than 30 days, a sample of 25 cull chicks produced from the flock shall be subjected to laboratory procedures acceptable to the Official State Agency and approved by the Service, for the detection and recovery of M. gallisepticum; or

(C) At intervals of not more than 30 days, egg yolk testing shall be conducted in accordance with § 147.8.

(2) A participant handling U.S. M. Gallisepticum Clean products shall

keep these products separate from other products in a manner satisfactory to the Official State Agency: *Provided*, That U.S. M. Gallisepticum Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (c)(1)(i) of this section are set.

(3) U.S. M. Gallisepticum Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in § 147.24(a) of this chapter.

(d) *U.S. Sanitation Monitored.* This program is intended to be the basis from which the breeding-hatching industry may conduct a program for the prevention and control of Salmonellosis. It is intended to reduce the incidence of Salmonella organisms in hatching eggs and chicks through an effective and practical sanitation program at the breeder farm and in the hatchery. This will afford other segments of the poultry industry an opportunity to reduce the incidence of Salmonella in their products.

(1) A flock and the hatching eggs and chicks produced from it which have met the following requirements as determined by the Official State Agency:

(i) The flock shall originate from a source where sanitation and management practices, as outlined in § 145.33(d)(1) of this paragraph, are conducted;

(ii) The flock is maintained in compliance with §§ 147.21, 147.24(a), and 147.26 of this chapter;

(iii) All feed should be pelletized and/or crumbled in mills operated at 190° F. or above in facilities for recontamination control;

(iv) Feed shall be stored and transported in such a manner as to prevent possible contamination;

(v) Hatching eggs are collected at least four times a day and are handled as described in § 147.22 and are fumigated on the farm as described in § 147.25(a) or otherwise sanitized; and

(vi) Chicks are hatched in a hatchery meeting the requirements of §§ 147.23 and 147.24(b) and are in compliance with § 147.25(b) of this chapter.

(2) The Official State Agency may use the procedures described in § 147.14 of this chapter to monitor the effectiveness of the sanitation practices.

(3) In order for a hatchery to sell products of this classification, all products handled shall meet the requirements of the classification.

(4) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.

(e) *U.S. M. Synoviae Clean.* (1) A flock maintained in compliance with the provisions of § 147.26 and in which freedom from M. synoviae has been demonstrated under the criteria specified in paragraph (e)(1) (i) or (ii) of this section.

(i) It is a flock in which a minimum of 300 birds has been tested for *M. synoviae* as provided in § 145.14(b) when more than 4 months of age: *Provided*, That to retain this classification, a sample of at least 150 birds shall be tested at intervals of not more than 90 days: *And provided further*, That a sample comprised of less than 150 birds may be tested at any one time, with the approval of the official State Agency and the concurrence of the Service, provided that a minimum of 150 birds is tested within each 90-day period; or

(ii) It is a multiplier breeding flock which originated as U.S. M. Synoviae Clean chicks from primary breeding flocks and from which a sample comprised of a minimum of 75 birds has been tested for *M. synoviae* as provided in § 145.14(b) when more than 4 months of age: *Provided*, That to retain this classification, the flock shall be subjected to one of the following procedures:

(*a*) At intervals of not more than 90 days, a sample of 50 birds shall be tested: *Provided*, That a sample of less than 50 birds may be tested at any one time, provided that a minimum of 30 birds per flock with a minimum of 15 birds per pen, whichever is greater, is tested each time and a total of at least 50 birds is tested within each 90-day period; or

(*b*) At intervals of not more than 30 days, egg yolk testing shall be conducted in accordance with § 147.8.

(2) A participant handling U.S. M. Synoviae Clean products shall keep these products separate from other products in a manner satisfactory to the official State Agency: *Provided*, That U.S. M. Synoviae Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (e)(1)(i) or (ii) of this section are set.

(3) U.S. M. Synoviae Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in § 147.24(a).

(f) *U.S. M. Gallisepticum Clean Started Poultry.* (1) A flock which originated from U.S. M. Gallisepticum Clean breeding flocks and was hatched in a hatchery approved by the Official State Agency for the production of U.S. M. Gallisepticum Clean chicks.

(2) All other poultry on the premises of the candidate flock must originate from U.S. M. Gallisepticum Clean sources.

(3) The flock is maintained in compliance with the provisions of § 147.26.

(4) The flock's freedom from *M. gallisepticum* is demonstrated by a negative blood test, as provided in § 145.14(b), of a sample of 75 birds, with a minimum of 50 birds per poultry house, between 15-20 days prior to the flock being moved to laying quarters.

(5) Started poultry shall be delivered to and from the farm premises in crates and vehicles which have been cleaned and disinfected as described in § 147.24(a) of this chapter.

(g) *U.S. M. Synoviae Clean Started Poultry.* (1) A flock which originated from U.S. M. Synoviae Clean breeding flocks and was hatched in a hatchery approved by the Official State Agency for the production of U.S. M. Synoviae Clean chicks.

(2) All other poultry on the premises of the candidate flock must originate from U.S. M. Synoviae Clean sources.

(3) The flock is maintained in compliance with the provisions of § 147.26.

(4) The flock's freedom from *M. synoviae* is demonstrated by a negative blood test, as provided in § 145.14(b), of a sample of 75 birds, with a minimum of 50 birds per poultry house, between 15-20 days prior to the flock being moved to laying quarters.

(5) Started poultry shall be delivered to and from the farm premises in crates and vehicles which have been cleaned and disinfected as described in § 147.24(a) of this chapter.

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§ 145.34 Terminology and classification; States.

(a) *U.S. Pullorum-Typhoid-Clean State.* (1) A State will be declared a U.S. Pullorum-Typhoid Clean State when it has been determined by the Service that:

(i) The State is in compliance with the provisions contained in § 145.23(b)(3)(i) through (vii), § 145.33(b)(3)(i) through (vii), § 145.43(b)(3)(i) through (vi), and § 145.53(b)(3)(i) through (vii).

(ii) No pullorum disease or fowl typhoid is known to exist nor to have existed in hatchery supply flocks within the State during the preceding 12 months: *Provided*, That pullorum disease or fowl typhoid found in waterfowl, exhibition poultry, and game bird breeding flocks will not prevent a State, which is otherwise eligible from qualifying for a period of two years.

(2) Discontinuation of any of the conditions described in paragraph (a)(1)(i) of this section, or repeated outbreaks of pullorum or typhoid occur in hatchery supply flocks described in paragraph (a)(1)(ii) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination that the State is entitled to this classification. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity for a hearing.

(b) *U.S. M. Gallisepticum Clean State, Meat-Type Chickens.* (1) A State will be declared a U.S. M. Gallisepticum Clean State, Meat-Type Chickens, when it has been determined by the Service that:

(i) No *M. gallisepticum* is known to exist nor to have existed in meat-type chicken breeding flocks in production within the State during the preceding 12 months;

(ii) All meat-type chicken breeding flocks in production are classified as U.S. M. Gallisepticum Clean or have met equivalent requirements for *M. gallisepticum* control under official supervision;

(iii) All hatcheries within the State which handle products from meat-type chicken breeding flocks only handle products which are classified as U.S. M. Gallisepticum Clean or have met equivalent requirements for *M. gallisepticum* control under official supervision;

(iv) All shipments of products from meat-type chicken breeding flocks other than those classified as U.S. M. Gallisepticum Clean, or equivalent, into the State are prohibited;

(v) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all specimens from chickens from meat-type chicken breeding flocks that have been identified as being infected with *M. gallisepticum*;

(vi) All reports of *M. gallisepticum* infection in chickens from meat-type chicken breeding flocks are promptly followed by an investigation by the Official State Agency to determine the origin of the infection;

(vii) All chickens from meat-type chicken breeding flocks found to be infected with *M. gallisepticum* are quarantined until marketed under supervision of the Official State Agency.

(2) Discontinuation of any of the conditions described in paragraph (b)(1) of this section, or if repeated outbreaks of *M. gallisepticum* occur in meat-type chicken breeding flocks described in paragraph (b)(1)(ii) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination that the State is entitled to this classification. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity for a hearing.

[40 FR 1503, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 50 FR 19899, May 13, 1985]

Subpart D—Special Provisions for Turkey Breeding Flocks and Products

§ 145.41 Definitions.

Except where the context otherwise requires, for the purposes of this subpart the following terms shall be construed, respectively, to mean:

(a) *Poults.* Newly hatched turkeys which have not been fed or watered.

[36 FR 23112, Dec. 3, 1971, as amended at 41 FR 48725, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 145.42 Participation.

(a) Participating turkey flocks, and the eggs and poults produced from them, shall comply with the applicable general provisions of Subpart A of this part and the special provisions of this Subpart D.

(b) The minimum weight of turkey hatching eggs shipped interstate shall be 2 ounces each for small varieties and 2½ ounces each for other varieties, unless otherwise specified by the purchaser of the eggs.

(c) Hatching eggs shall be fumigated as described in § 147.25 or otherwise sanitized.

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13707, May 24, 1973; 40 FR 1503, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19802, May 10, 1984]

§ 145.43 Terminology and classification; flocks and products.

Participating flocks, and the eggs and poults produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in § 145.10:

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the official State agency under the criteria in one of the following paragraphs (b) (1) through (5) of this section: *Provided*, That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be at the discretion of the official State agency with the concurrence of the Service. (See § 145.14 relating to the official blood test where applicable.)

(1) It has been officially blood tested with no reactors.

(2) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, and meets the following specifications as determined by the Official State Agency and the Service:

(i) The flock is located in a State where all persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum or S. gallinarum is isolated;

(ii) The flock is composed entirely of birds that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision; and

(iii) A sample comprised of at least 25 percent of the birds in the flock has been officially blood tested with no reactors, or its progeny has been subjected to an approved 10-day poult mortality bacteriological examination monitoring program and bacteriological examination of a sample of down shed by poults in the hatcher from selected hatches as prescribed by the Official State Agency: *Provided*, That when the blood testing procedure is used, the percentage of the flock included in the sample may be reduced by 5 percentage points following each year in which there is no evidence of infection on the premises until the required percentage is reduced to zero: *And provided further*, That the sample tested for the qualification of a flock under this subparagraph shall include at least 500 birds the first year, 400 the second year, 300 the third year, 200 the fourth year, and 100 the fifth year.

(3) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision, and is located in a State in which it has been determined by the Service that:

(i) All turkey hatcheries within the State are qualified as "National Plan Hatcheries" or have met equivalent requirements for pullorum-typhoid control under official supervision;

(ii) All turkey hatchery supply flocks within the State are qualified as U.S. Pullorum-Typhoid Clean or have met equivalent requirements for pullorum-typhoid control under official supervision: *Provided*, That if other domesticated fowl, except waterfowl, are maintained on the same premises as the participating flock, freedom from pullorum-typhoid infection shall be demonstrated by an official blood test of each of these fowl;

(iii) All shipments of products other than U.S. Pullorum-Typhoid Clean, or equivalent, into the State are prohibited;

(iv) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum or S. gallinarum is isolated;

(v) All reports of S. pullorum or S. gallinarum isolations from poultry are promptly followed by an investigation by the Official State Agency to determine the origin of the infection;

(vi) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested, following the procedure for reacting flocks as contained in § 145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

(vii) [Reserved]

(viii) Discontinuation of any of the conditions or procedures described in paragraphs (b)(3) (i), (ii), (iii), (iv), (v), and (vi) of this section, or the occurrence of repeated outbreaks of pullorum or typhoid in turkey breeding flocks within or originating within the State shall be grounds for the Service to revoke its determination that such conditions and procedures have been met or complied with. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity to present its views.

(4) It is a multiplier breeding flock located in a State which has been determined by the Service to be in compliance with the provisions of paragraph (b)(3) of this section and in which pullorum disease or fowl typhoid is not known to exist nor to have existed in turkey hatchery supply flocks within the State during the preceding 24 months.

(5) It is a primary breeding flock located in a State determined to be in compliance with the provisions of paragraph (b)(4), of this section and in which a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with no reactors: *Provided*, That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of blood testing.

(c) *U.S. M. Gallisepticum Clean.* (1) A flock maintained in accordance with the conditions and procedures described in § 147.26 of this chapter, and in which no reactors are found when a random sample of at least 10 percent of the birds in the flock, or 300 birds in flocks of more than 300 and each bird in flocks of 300 or less, is tested when more than 4 months of age, in accordance with the procedures described in § 145.14(b).

(2) A flock qualified as U.S. M. Gallisepticum Clean may retain the classification through its first egg-laying cycle, provided it is maintained in isolation and no evidence of *M. gallisepticum* infection is revealed. A flock which is molted following completion of an egg-laying cycle and subsequently brought back into production, shall be retested within 2 weeks prior to production, as described in paragraph (c)(1) of this section. A State inspector shall visit with the owner or manager of each flock at least once during each laying cycle to discuss and ascertain whether the applicable conditions outlined in § 147.26 of this chapter are being met. If a flock proves to be infected with *M. gallisepticum*, it shall lose this classification.

(3) In order to sell hatching eggs or poults of this classification, all hatching eggs and poults handled by the participant must be of this classification.

(d) *U.S. M. Meleagridis Clean.* (1) A block in which freedom from *M. meleagridis* has been demonstrated under the following criteria:

(i) A sample of 60 birds from each flock has been tested for *M. meleagridis* when more than 4 months of age: *Provided*, That to retain this classification, a minimum of 30 samples from male flocks and 60 samples from female flocks shall be retested at 28–30 weeks of age and at 4–6 week intervals thereafter.

(2) The official blood tests for *M. meleagridis* shall be the serum plate agglutination test, the tube agglutination test, or the microagglutination test. The hemagglutination inhibition (HI) test, microhemagglutination inhibition test, serum plate dilution test, microagglutination test and the enzyme-labeled immunosorbent assay (ELISA)[3] test may be used as supple-

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[3] Procedures for the enzyme-labeled immunosorbent assay (ELISA) test are set forth in the following publications:

A.A. Ansari, R.F. Taylor, T.S. Chang, "Application of Enzyme-Linked Immunosorbent Assay for Detecting Antibody to Mycoplasma gallisepticum Infections in Poultry," *Avian Diseases*, Vol. 27, No. 1, pp. 21–35, January-March 1983; and

H.M. Opitz, J.B. Duplessis, and M.J. Cyr, "Indirect Micro-Enzyme-Linked Immunosorbent Assay for the Detection of Antibodies to Mycoplasma synoviae and M. gallisepticum," *Avian Diseases*, Vol. 27, No. 3, pp. 773–786, July-September 1983; and

H.B. Ortmayer and R. Yamamoto, "Mycoplasma Meleagridis Antibody Detection by

Continued

mental tests to determine the status of the flock, in accordance with § 147.6(b).

(3) The tests shall be conducted using *M. meleagridis* antigens and the protocols for testing approved by the Department or the Official State Agency.

(4) When reactors to the official test are found and can be identified, 10 tracheal swabs and/or vaginal or phallus swabs and their corresponding blood samples shall be submitted to a laboratory for serological and cultural examination. If reactors cannot be identified, at least 30 tracheal swabs and/or vaginal or phallus swabs and their corresponding blood samples shall be submitted. In a flock with a low reactor rate (less than 5 reactors) the reactors may be submitted to the laboratory within 10 days for serology, necropsy, and thorough bacteriological examination.

(5) If a mycoplasma is isolated, the organism must be serotyped. If *M. meleagridis* is isolated, the block shall be considered infected.

(e) *U.S. M. Synoviae Clean.* (1) All birds, or a sample of at least 100 birds from flocks of more than 100 and each bird in flocks of 100 or less, have been tested for *M. synoviae* when more than 4 months of age in accordance with the procedures in § 145.14(b): *Provided,* That to retain this classification a minimum of 30 samples from male flocks and 60 samples from female flocks shall be retested at 28-30 weeks of age and at 4-6 week intervals thereafter.

(2) When reactors to the official test are found and can be identified, tracheal swabs and their corresponding blood samples from 10 (all if fewer than 10) reacting birds shall be submitted to an authorized laboratory for serological and cultural examination. If reactors cannot be identified, at least 30 tracheal swabs and their corresponding blood samples shall be submitted. In a flock with a low reactor rate (less than five reactors) the reactors may be submitted to the laboratory within 10 days for serology, necropsy, and thorough bacteriological examination. When reactors to the official test are found, the procedures outlined in § 147.6 will be used to determine the status of the flock.

(3) Flocks located on premises which, during 3 consecutive years, have contained breeding flocks qualified as U.S. M. Synoviae Clean, as described in paragraph (e)(1) above, may qualify for this classification by a negative blood test of at least 100 birds from flocks of more than 100 and each bird in flocks of 100 or less, when more than 4 months of age, and by testing a minimum of 30 samples from male flocks and 60 samples from female flocks at 28-30 weeks of age and at 45 weeks of age.

(Approved by the Office of Management and Budget under control number 0579-0007)

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13707, May 24, 1973; 40 FR 1503, Jan. 8, 1975; 41 FR 14256, Apr. 2, 1976; 41 FR 48725, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 47 FR 21993, May 20, 1982; 47 FR 23431, May 28, 1982; 48 FR 57473, Dec. 30, 1983; 49 FR 19802, May 10, 1984; 50 FR 19899, May 13, 1985]

§ 145.44 Terminology and classification; States.

(a) *U.S. Pullorum-Typhoid Clean State.* (1) A State will be declared a U.S. Pullorum-Typhoid Clean State when it has been determined by the Service that:

(i) The State is in compliance with the provisions contained in § 145.23(b)(3)(i) through (vii), § 145.33(b)(3)(i) through (vii), § 145.43(b)(3)(i) through (vi), and § 145.53(b)(3)(i) through (vii).

(ii) No pullorum disease or fowl typhoid is known to exist nor to have existed in hatchery supply flocks within the State during the preceding 12 months: *Provided,* That pullorum disease or fowl typhoid found in waterfowl, exhibition poultry, and game bird breeding flocks will not prevent a State, which is otherwise eligible, from qualifying for a period of two years.

(2) Discontinuation of any of the conditions described in paragraph (a)(1)(i) of this section, or repeated outbreaks of pullorum or typhoid

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Enzyme-Linked Immunosorbent Assay (ELISA)," *Proceedings, 30th Western Poultry Disease Conference,* pp. 63-66, March 1981.

occur in hatchery supply flocks described in paragraph (a)(1)(ii) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination that the State is entitled to this classification. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity for a hearing.

(b) *U.S. Pullorum-Typhoid Clean State, Turkeys.* (1) A State will be declared a U.S. Pullorum-Typhoid Clean State, Turkeys, when it has been determined by the Service that:

(i) The State is in compliance with the provisions contained in § 145.43(b)(3)(i) through (vi).

(ii) No pullorum disease or fowl typhoid is known to exist nor to have existed in turkey hatchery supply flocks within the State during the preceding 24 months.

(2) Discontinuation of any of the conditions described in paragraph (b)(1)(i) of this section, or repeated outbreaks of pullorum or typhoid occur in hatchery supply flocks described in paragraph (b)(1)(ii) of this section, or if an infection spreads from the originating premises, Service shall have grounds to revoke its determination that the State is entitled to this classification. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity for a hearing.

(c) *U.S. M. Gallisepticum Clean State, Turkeys.* (1) A State will be declared a U.S. M. Gallisepticum Clean State, Turkeys when it has been determined by the Service that:

(i) No M. gallisepticum is known to exist nor to have existed in turkey breeding flocks in production within the State during the preceding 12 months.

(ii) All turkey breeding flocks in production are classified as U.S. M. Gallisepticum Clean or have met equivalent requirements for M. gallisepticum control under official supervision.

(iii) All turkey hatcheries within the State handle products which are classified as U.S. M. Gallisepticum Clean or have met equivalent requirements for M. gallisepticum control under official supervision.

(iv) All shipments of turkey products other than those classified as U.S. M. Gallisepticum Clean, or equivalent, into the State are prohibited.

(v) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all turkey specimens that have been identified as being infected with M. gallisepticum.

(vi) All reports of M. gallisepticum infection in turkeys are promptly followed by an investigation by the Official State Agency to determine the origin of the infection.

(vii) All turkey flocks found to be infected with M. gallisepticum are quarantined until marketed under supervision of the Official State Agency.

(2) Discontinuation of any of the conditions described in paragraph (c)(1) of this section, or if repeated outbreaks of M. gallisepticum occur in turkey breeding flocks described in paragraph (c)(1)(ii) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination that the State is entitled to this classification. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity for a hearing.

(3) If a State retains this status for 2 or more years, individual breeding flocks in the State may qualify for an *M. gallisepticum* classification based on a negative test of a sample of 100 birds.

(Approved by the Office of Management and Budget under control number 0579-0007)

[40 FR 1503, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 45 FR 10316, Feb. 15, 1980; 48 FR 57473, Dec. 30, 1983; 49 FR 19803, May 10, 1984]

Subpart E—Special Provisions for Waterfowl, Exhibition Poultry, and Game Bird Breeding Flocks and Products

§ 145.51 Definitions.

Except where the context otherwise requires, for the purposes of this subpart the following terms shall be construed, respectively, to mean:

(a) *Waterfowl.* Domesticated fowl that normally swim, such as ducks and geese.

(b) *Exhibition Poultry.* Domesticated fowl which are bred for the combined purposes of meat or egg production and competitive showing.

(c) *Game birds.* Domesticated fowl such as pheasants, partridge, quail, grouse, and guineas, but not doves and pigeons.

§ 145.52 Participation.

Participating flocks of waterfowl, exhibition poultry, and game birds, and the eggs and baby poultry produced from them shall comply with the applicable general provisions of Subpart A of this part and the special provisions of this Subpart E.

(a) Started poultry shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in § 145.5(a).

(b) Hatching eggs produced by primary breeding flocks shall be fumigated as described in § 147.25 or otherwise sanitized.

[36 FR 23112, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19803, May 10, 1984]

§ 145.53 Terminology and classification; flocks and products.

Participating flocks, and the eggs and baby poultry produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in § 145.10.

(a) *U.S. Approved.* All birds in the breeding flock observed by Authorized Agents or State Inspectors are found to conform with the criteria for the breed represented, as contained in the Standard of Perfection[1] or the breeder's specifications for the stock represented in the flock, and such specifications are on file with the Official State Agency.

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in one of the following paragraphs (b)(1) through (5) of this section (See § 145.14 relating to the official blood test where applicable.):

(1) It has been officially blood tested within the past 12 months with no reactors.

(2) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, and meets the following specifications as determined by the Official State Agency and the Service:

(i) The flock is located in a State where all persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum or S. gallinarum is isolated;

(ii) The flock is composed entirely of birds that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision; and

(iii) A sample comprised of at least 25 percent of the birds in the flock has been officially blood tested within the past 12 months with no reactors, or its progeny has been subjected to an approved 10-day baby poultry mortality bacteriological examination monitoring program and bacteriological examination of a sample of down shed by baby poultry in the hatcher from selected hatches as prescribed by the Official State Agency: *Provided,* That when the blood testing procedure is used, the percentage of the flock included in the sample may be reduced by 5 percentage points following each year in which there is no evidence of infection on the premises until the required percentage is reduced to zero: *And provided further,* That the sample tested for the qualification of a flock under this subparagraph shall include at least 500 birds the first year, 400 the second year, 300 the third year, 200 the fourth year, and 100 the fifth year.

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[1] Published by the American Poultry Association, Inc.

(3) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision, and is located in a State in which it has been determined by the Service that:

(i) All hatcheries, except turkey hatcheries, within the State are qualified as "National Plan Hatcheries" or have met equivalent requirements for pullorum-typhoid control under official supervision;

(ii) All hatchery supply flocks, except turkey flocks, within the State, are qualified as U.S. Pullorum-Typhoid Clean or have met equivalent requirements for pullorum-typhoid control under official supervision: *Provided,* That if other domesticated fowl, except waterfowl, are maintained on the same premises as the participating flock, freedom from pullorum-typhoid infection shall be demonstrated by an official blood test of each of these fowl;

(iii) All shipments of products other than U.S. Pullorum-Typhoid Clean, or equivalent, into the State are prohibited;

(iv) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum or S. gallinarum is isolated;

(v) All reports of S. pullorum or S. gallinarum isolations from poultry are promptly followed by an investigation by the Official State Agency to determine the origin of the infection;

(vi) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested, following the procedure for reacting flocks as contained in § 145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

(vii) All poultry, including exhibition, exotic, and game birds, but excluding waterfowl, going to public exhibition shall come from U.S. Pullorum-Typhoid Clean or equivalent flocks, or have had a negative pullorum-typhoid test within 90 days of going to public exhibition;

(viii) Discontinuation of any of the conditions or procedures described in paragraphs (b)(3)(i), (ii), (iii), (iv), (v), (vi), and (vii) of this section, or the occurrence of repeated outbreaks of pullorum or typhoid in poultry breeding flocks, other than turkey flocks, within or originating within the State shall be grounds for the Service to revoke its determination that such conditions and procedures have been met or complied with. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity to present its views.

(4) It is a multiplier breeding flock located in a State which has been determined by the Service to be in compliance with the provisions of paragraph (b)(3) of this section, and in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks, other than turkey flocks, within the State during the preceding 24 months.

(5) It is a primary breeding flock located in a State determined to be in compliance with the provisions of paragraph (b)(4) of this section, and in which a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid within the past 12 months with no reactors: *Provided,* That a bacteriological examination monitoring program or serologial examination monitoring program for game birds acceptable to the Official State Agency and approved by the Service may be used in lieu of annual blood testing: *And Provided further,* That when a flock is a

waterfowl or exhibition poultry primary breeding flock located in a State which has been deemed to be a U.S. Pullorum-Typhoid Clean State for the past three years, and during which time no isolation of pullorum or typhoid has been made that can be traced to a source in that State, a bacteriological examination monitoring program or a serological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of annual blood testing.

(c) *U.S. M. Gallisepticum Clean.* (1) A flock maintained in compliance with the provisions of § 147 .26 of this chapter and in which freedom from M. gallisepticum has been demonstrated under the criteria specified in paragraph (c)(1)(i) or (ii) of this section.

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for *M. gallisepticum* as provided in § 145.14(b) when more than 4 months of age or upon reaching sexual maturity: *Provided,* That to retain this classification, a sample of at least 5 percent of the birds in the flock, with a minimum of 100 birds, shall be tested at intervals of not more than 90 days: *And provided further,* That a sample comprised of less than 5 percent may be tested at any one time, with the approval of the Official State Agency and the concurrence of the Service, provided that a total of at least 5 percent of the birds in the flock, with a minimum of 100 birds, is tested within each 90-day period; or

(ii) It is a multiplier breeding flock which originated as U.S. M. Gallisepticum Clean baby poultry from primary breeding flocks and a random sample comprised of 50 percent of the birds in the flock, with a maximum of 200 birds and a minimum of 30 birds per flock, has been tested for M. gallisepticum as provided in § 145.14(b) when more than 4 months of age or upon reaching sexual maturity: *Provided,* That to retain this classification, the flock shall be subjected to one of the following procedures:

(A) At intervals of not more than 90 days, a random sample of at least 2 percent of the birds in the flock, with a minimum of 30 birds per pen, shall be tested; or

(B) At intervals of not more than 30 days, a sample of 25 cull baby poultry produced from the flock shall be subjected to laboratory procedures acceptable to the Official State Agency and approved by the Service, for the detection and recovery of M. gallisepticum; or

(2) A participant handling U.S. M. Gallisepticum Clean products shall keep these products separate from other products in a manner satisfactory to the Official State Agency: *Provided,* That U.S. M. Gallisepticum Clean baby poultry from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (c)(1)(i) of this section are set.

(3) U.S. M. Gallisepticum Clean baby poultry shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in § 147.24(a) of this chapter.

(Approved by the Office of Management and Budget under control number 0579-0007)

[36 FR 23112, Dec. 3, 1971, as amended at 40 FR 1503, Jan. 8, 1975; 41 FR 48725, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 47 FR 21993, May 29, 1982; 48 FR 57473, Dec. 30, 1983; 50 FR 19900, May 13, 1985]

§ 145.54 Terminology and classification; States.

(a) *U.S. Pullorum-Typhoid Clean State.* (1) A State will be declared a U.S. Pullorum-Typhoid Clean State when it has been determined by the Service that:

(i) The State is in compliance with the provisions contained in § 145.23(b)(3)(i) through (vii), § 145.33(b)(3)(i) through (vii), § 145.43(b)(3)(i) through (vi), and § 145.53(b)(3)(i) through (vii).

(ii) No pullorum disease or fowl typhoid is known to exist nor to have existed in hatchery supply flocks within the State during the preceding 12 months: *Provided,* That pullorum disease or fowl typhoid found in waterfowl, exhibition poultry, and game bird breeding flocks will not prevent a State, which is otherwise eligible, from qualifying for a period of two years.

(2) Discontinuation of any of the conditions described in paragraph (a)(1)(i) of this section, or repeated outbreaks of pullorum or typhoid occur in hatchery supply flocks described in paragraph(a)(1)(ii) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination that the State is entitled to this classification. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity for a hearing.

[40 FR 1504, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979]

PART 146—[RESERVED]

PART 147—AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT PLAN

Subpart A—Blood Testing Procedures

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AUTHORITY: 7 U.S.C. 429; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 36 FR 23121, Dec. 3, 1971, unless otherwise noted. Redesignated at 44 FR 61586, Oct. 26, 1979.

EDITORIAL NOTE: For nomenclature changes, see 44 FR 61586, Oct. 26, 1979.

Subpart A—Blood Testing Procedures

§ 147.1 The standard tube agglutination test.[1]

(a) The blood samples should be collected and delivered as follows:

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[1] The procedure described is a modification of the method reported in the Proceedings of the U.S. Live Stock Sanitary Association, November 30 to December 2, 1932, pp. 487 to 491.

(1) The blood samples should be taken by properly qualified and authorized persons only, and in containers provided by the laboratory. The containers should be stout-walled test tubes, preferably ⅜ by 3 inches, without lip, or small well-selected medicine vials, which have been thoroughly cleaned and dried in a hot-air drying oven. If stoppers are used, they should be thoroughly cleaned and dried.

(2) Sufficient blood should be procured by making a small incision in the large median wing vein with a small sharp lancet and allowing the blood to run into the tube, or by the use of a small syringe (with 20 or 21 gage needle) which is properly cleansed between bleedings with physiological saline solution. To facilitate the separation of the serum, the tubes should be placed in a slanted position until the blood has solidified. After the blood has completely clotted, they should be packed and shipped by mail (special delivery), rapid express, or by messenger, to the laboratory. All labeling must be clear and permanent, and may be done with a suitable pencil on etched portions of the tube, or by means of fast-gum labels.

(3) The blood samples must reach the laboratory in a fresh and unhemolyzed condition. Hemolyzed samples should be rejected. It is imperative, therefore, to cool the tubes immediately after slanting and clotting, and unless they reach the laboratory within a few hours, to pack them with ice in special containers, or use some other cooling system which will insure their preservation during transportation. In severe cold seasons, extreme precautions must be exercised to prevent freezing and consequent laking. The samples must be placed in cold (5° to 10° C.) storage, immediately upon arrival at the laboratory.

(b) The antigen shall consist of representative strains of S. pullorum which are of known antigenic composition, high agglutinability, but are not sensitive to negative and nonspecific sera. The stock cultures may be maintained satisfactorily by transferring to new sloped agar at least once a month and keeping at 18° to 25° C. (average room temperature) in a dark closet or chest, following incubation for from 24 to 36 hours at 37° C. The antigenic composition and purity of the stock cultures should be checked consistently.

(c) A medium which has been used satisfactorily has the following composition:

Water	1,000 cc.
Difco beef extract	4 gm. (0.4 percent).
Difco Bacto-peptone	10 gm. (1.0 percent).
Difco dry-granular agar	20 gm. (2.0 percent).

Reaction—pH 6.8 to 7.2.

(d) Large 1-inch test tubes, Kolle flasks, or Blake bottles should be streaked liberally over the entire agar surface with inoculum from 48-hour slant agar cultures prepared from the stock cultures of the selected strains. The antigen-growing tubes or bottles should be incubated 48 hours at 37° C., and the surface growth washed off with sufficient phenolized (0.5 percent) saline (0.85 percent) solution to make a heavy suspension. The suspension should be filtered free of clumps through a thin layer of absorbent cotton in a Buchner funnel with the aid of suction. The antigens of the separate strains should be combined in equal volume-density and stored in the refrigerator (5° to 10° C.) in tightly stoppered bottles.

(e) Thiosulfate-Glycerin (TG) medium may be used as an alternate medium for the preparation of tube agglutination antigen. The TG medium, formerly used for the preparation of stained, whole-blood antigen, is described in more detail in the article by A. D. MacDonald, Recent Developments in Pullorum Antigen for the Rapid, Whole-Blood Test, Report of the Conference of the National Poultry Improvement Plan, pages 122-127, 1941. This medium provides a tube antigen of excellent specificity and greatly increases the yield of antigen from a given amount of medium. The TG medium has the following composition:

Beef infusion	1,000 cc.
Difco Bacto-peptone	20 gm. (2.0 percent).
Sodium thiosulfate	5 gm. (0.5 percent).
Ammonium chloride	5 gm. (0.5 percent).
Glycerin, U.S.P. (95 percent)	20 cc. (2.0 percent).
Difco dry-granular agar	30 gm. (3.0 percent).

Reaction—pH 6.8 to 7.2.

Large 1-inch test tubes, Kolle flasks, Blake bottles, or Erlenmeyer flasks should be seeded over the entire agar surface with inoculum from 24-hour beef infusion broth cultures prepared from the stock cultures of the selected strains. The antigen-growing tubes or bottles should be incubated 96 hours at 37° C., and the surface growth washed off with sufficient phenolized (0.5 percent) saline (0.85 percent) solution to make a heavy suspension. The suspension should be filtered free of clumps through a thin layer of absorbent cotton in a Buchner funnel with the aid of suction. The antigen then should be centrifuged. The mass of bacteria should be removed from the centrifuge tubes or bowl and resuspended in saline (0.85 percent) solution containing 0.5 percent phenol. After the bacterial mass has been uniformly suspended in the diluent, it should be again passed through a cotton pad in a Buchner funnel without the aid of suction. The antigens of the separate strains should be combined in equal volume-density and stored in the refrigerator (5° to 10° C.) in tightly stoppered bottles.

(f) The diluted antigen to be used in the routine testing should be prepared from the stock antigen by dilution of the latter with physiological (0.85 percent) saline solution containing 0.25 percent of phenol to a turbidity corresponding to 0.75–1.00 on the McFarland nephelometer scale. The hydrogen-ion concentration of the diluted antigen should be corrected to pH 8.2 to 8.5 by the addition of dilute sodium hydroxide. New diluted antigen should be prepared each day and kept cold. The diluted antigen may be employed in 2 cc. quantities in 4 by ½-inch test tubes, or 1 cc. quantities in smaller tubes, in which the final serum-antigen mixtures are made and incubated. The distribution of the antigen in the tubes may be accomplished by the use of long burettes, or special filling devices made for the purpose.

(g) The maximum serum dilution employed must not exceed 1:50 for chickens, nor 1:25 for turkeys. The available data indicate that 1:25 dilution is the most efficient. In all official reports on the blood test, the serum dilutions shall be indicated. The sera should be introduced into the agglutination tubes in the desired amounts with well-cleaned serological pipettes or special serum-delivery devices which do not permit the mixing of different sera. The antigen and serum should be well mixed before incubation. The serum and antigen mixture must be incubated for at least 20 hours at 37° C.

(h) The results shall be recorded as:

N, or – (negative) when the serum-antigen mixture remains uniformly turbid.

P, or + (positive) when there is a distinct clumping of the antigen, and the liquid between the agglutinated particles is clear.

S, or ? (suspicious) when the agglutination is only partial or incomplete.

M, or missing, when samples listed on the original record sheet are missing.

H, or hemolyzed, when blood samples are hemolyzed and cannot be tested.

B, or broken, when sample tubes are broken and no serum can be obtained.

(Some allowance must always be made for the difference in sensitiveness of different antigens and different set-ups, and therefore, a certain amount of independent, intelligent judgment must be exercised at all times. Also, the histories of the flocks require consideration. In flocks where individuals show a suspicious agglutination, it is desirable to examine representative birds bacteriologically to determine the presence or absence of S. pullorum.)

§ 147.2 The rapid serum test.[2]

(a) The procedure for the collection and delivery of blood samples in the rapid serum test is the same as that described in § 147.1(a).

(b) The selection and maintenance of suitable strains of S. pullorum and the composition of a satisfactory medium are described in § 147.1 (b) and (c).

(c) Large 1-inch test tubes, Kolle flasks, or Blake bottles are streaked liberally from 48-hour slant-agar cultures prepared from stock cultures of the selected strains.

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[2] The procedure described is a modification of the method reported by Runnels, Coon, Farley, and Thorpe, Amer. Vet. Med. Assoc. Jour. 70 (N.S. 23): 660-662 (1927).

(d) The antigen-growing tubes or bottles should be incubated 48 hours at 37° C., and the surface growth washed off with a very slight amount of 12 percent solution of sodium chloride containing 0.25 to 0.5 percent phenol, filtered through lightly packed sterile absorbent cotton placed in the apex of a sterile funnel.

(e) The washings should be adjusted (using 12 percent sodium chloride containing 0.25 to 0.5 percent phenol) so that the turbidity is 50 times greater than tube 0.75 of McFarland's nephelometer, or to a reading of 7 mm. by the Gates nephelometer.

(f) The individual strain antigens should be tested with negative sera for their insensitivity and with positive sera for high agglutinability in comparison with known satisfactory antigen. The antigens of the separate strains should be combined in equal volume-density and stored in the refrigerator (5° to 10° C.) in tightly stoppered bottles.

(g) The tests should be conducted on a suitable, smooth plate. The serum-antigen dilution should be made so that the dilution will not exceed 1:50 when compared to the standard tube agglutination test. When testing turkey blood samples, it is desirable to use a serum-antigen dilution equivalent to the 1:25 in the tube method. The serum should be added to the antigen and mixed thoroughly by use of the tip of the serum pipette. Most strong positive reactions will be plainly evident within 15 to 20 seconds. The final reading should be made at the end of 2 or 3 minutes. Heating the plate at approximately 37° C. will hasten agglutination. Before reading, the plate should be rotated several times.

(h) The results shall be recorded as described in § 147.1(h).

§ 147.3 The stained-antigen, rapid, whole-blood test.[3]

(a) The description of the preparation of antigen is not herein included because the antigen is a proprietary product produced only under license from the Secretary of Agriculture.

(b) A loop for measuring the correct quantity of blood can usually be obtained from the manufacturer of the antigen. A satisfactory loop may be made from a piece of No. 20 gage nichrome wire, 2½ inches long, at the end of which is fashioned a loop three-sixteenths of an inch in diameter. Such a loop, when filled with blood so that the blood appears to bulge, delivers 0.02 cc. A medicine dropper whose tip is adjusted to deliver 0.05 cc. is used to measure the antigen. A glass plate about 15 inches square, providing space for 48 tests, has proved satisfactory for this work. The use of such a plate enables the tester to have a number of successive test mixtures under observation without holding up the work to wait for results before proceeding to the next bird.

(c) A drop of antigen should be placed on the testing plate. A loopful of blood should be taken up from the wing vein. When submerged in the blood and then carefully withdrawn, the loop becomes properly filled. On looking down edgewise at the filled loop, one observes that the blood appears to bulge. The loopful of blood then should be stirred into the drop of antigen, and the mixture spread to a diameter of about 1 inch. The loop then should be rinsed in clean water and dried by touching it to a piece of clean blotting paper, if necessary. The test plate should be rocked from side to side a few times to mix the antigen and blood thoroughly, and to facilitate agglutination. The antigen should be used according to the directions of the producer.

(d) Various degrees of reaction are observed in this as in other agglutination tests. The greater the agglutinating ability of the blood, the more rapid the clumping and the larger the clumps. A positive reaction consists of a definite clumping of the antigen surrounded by clear spaces. Such reaction is easily distinguished against a white background. A somewhat weaker reaction consists of small but still clearly visible clumps of antigen surrounded by spaces only partially clear. Between this point and a negative or homogeneous smear, there sometimes occurs a very fine granulation barely visible to the naked eye; this should be disregarded in making a diagnosis. The very fine marginal clumping which may occur just before drying up is also regarded as negative. In a nonreactor, the smear remains homogeneous. (Allowance should be made for differences in the sensitiveness of different antigens and different set-ups, and therefore, a certain amount of independent, intelligent judgment must be exercised at all times. Also, the histories of the flocks require consideration. In flocks where individuals show a suspicious agglutination, it is desirable to examine representative birds bacteriologically to determine the presence or absence of S. pullorum.)

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[3] The procedure described is a modification of the method reported by Schaffer, MacDonald, Hall, and Bunyea, Jour. Amer. Vet. Med. Assoc. 79 (N. S. 32): 236-240 (1931).

§ 147.4 The tube agglutination test for S. typhimurium.

(a) The procedure for the collection and delivery of blood samples in the tube agglutination test for S. typhimurium is the same as that described in § 147.1(a).

(b) The "O" antigen should be prepared as follows:

(1) The antigen shall consist of a representative nonmotile strain of S. typhimurium which is of known antigenic composition and high agglutinability but is not sensitive to negative and nonspecific sera. Strain P 10 meets these requirements.

(2) The stock culture is maintained on 1 percent nutrient agar deeps, which have been incubated for 18-24 hours at 37° C. They are stored at room temperature.

(3) A satisfactory medium used for growing the organism is veal infusion agar (Difco). It is dispensed in 50 ml. amounts into 500 ml. medicine bottles, with screw caps, and sterilized at 15 pounds pressure for 20 minutes. The bottles are then laid flat upon an even surface until the medium has solidified.

(4) The inoculum used for preparation of "O" antigen is a nonmotile strain of S. typhimurium. The organism is grown in veal infusion broth (Difco) for 18-24 hours at 37° C.; then plated, for single colony isolation, on veal infusion agar plates. These plates are incubated for 18-24 hours at 37° C. After incubation, single colonies are picked and transferred to veal infusion agar slants, which are incubated for 18-24 hours at 37° C. After this, the cultures are tested for smoothness by using a 1:500 dilution of acriflavine.

(5) Smooth cultures are inoculated into flasks containing veal or beef infusion broth which is incubated for 18-24 hours at 37° C. The incubated broth suspension of organisms is dispensed into the antigen bottles containing veal infusion agar. The suspension is distributed evenly over the agar surface by gently tilting the bottles from side to side. The inoculated bottles are then laid flat, agar side down, for 10-20 minutes. They are subsequently incubated, agar side upward, for 24-48 hours at 37° C. before harvesting.

(6) The harvesting of the organism consists of washing the growth from each antigen bottle with 0.5 percent phenolized physiological saline. The bacterial suspension from each bottle is filtered through sterile milk pad filters into a large sterile container or through a thin layer of absorbent cotton in a Buchner funnel with the aid of suction. To each 100 ml. of the bacterial suspension is added additional phenol to make the final concentration 0.5 percent. The concentrated antigen is tested for sterility at intervals after 24 hours. After sterility is proved, the stock antigen is standardized to determine the density according to the McFarland nephelometer scale.

(7) The diluted antigen to be used in routine testing is prepared from stock antigen, by diluting with 0.25 percent phenolized saline, and is standardized to a turbidity corresponding to 0.75-1.00 of the McFarland nephelometer scale.

(c) The maximum serum dilution employed for the "O" antigen tube test must not exceed 1:25. In all official reports on the blood test, the serum dilutions should be indicated. The sera should be introduced into the agglutination tubes in the desired amounts with well-cleaned serological pipettes or special serum delivery devices which do not permit the mixing of different sera. The antigen and serum should be well mixed before incubation. The serum and antigen mixture must be incubated for at least 20 hours at 37° C.

(d) The results shall be recorded as described in § 147.1(h).

§ 147.5 The microagglutination test for pullorum-typhoid.

Routinely, the microagglutination test is applied as a single-dilution test and only a single 18-24 hour reading is made.

(a) The procedure for the collection and delivery of blood samples in the microagglutination test is the same as that described in § 147.1(a). A method that has proven advantageous is to transfer the serum samples from the blood clot to a microplate as described in "Applied Microbiology," volume 24, No. 4, October 1972, pages 671-672. The dilutions are then performed according to paragraphs (d) or (e) of this section.

(b) Stained microtest antigen for pullorum-typhoid is supplied as concentrated stock suspension and must be approved by the Department.[1] Directions for diluting will be provided with the antigen. The stock as well as the diluted antigen prepared each day should be kept sealed in the dark at 5° to 10° C. when not in use.

(c) Available data indicate that a 1:20 dilution for the microagglutination test is most efficient for the detection of pullorum-typhoid agglutinins in both chickens and turkeys. In all official reports on the blood test, the serum dilutions shall be indicated.

(d) The recommended procedure for the 1:20 dilution in the microagglutination test is as follows:

(1) Add 100 microliters (0.10 cc.) of 0.85 percent physiological saline to each well of the microplate.

(2) Using a microdiluter or a multimicrodiluter handle fitted with twelve 10 microliter microdiluters, transfer 10 microliters (0.01 cc.) of the serum sample from the collected specimen to the corresponding well of the microplate. This is accomplished by touching the surface of the serum sample with the microdiluter and then transferring and mixing with the diluent in the microplate well. The microdiluter is removed, blotted, touched to the surface of the distilled water wash, and again blotted. Other acceptable methods of serum delivery are described in "Applied Microbiology," volume 21, No. 3, March 1971, pages 394-399.

(3) Dilute the microtest antigens with 0.50 percent phenolized saline and add 100 microliters (0.1 cc.) to each microplate well.

(4) Seal each plate with a plastic sealer or place unsealed in a tight incubation box as described in "Applied Microbiology," volume 23, No. 5, May 1972, pages 931-937. Incubate at 37°C. for 18-24 hours.

(5) Read the test results as described in paragraph (f) of this section.

(e) The recommended procedure for a microagglutination test titration is as follows:

(1) Add 50 microliters (0.05cc.) of 0.85 percent physiological saline to each well of the microplate.

(2) To the wells representative of the lowest dilution in the titration, add an additional 50 microliters (0.05 cc.) of 0.85 percent physiological saline making a total of 100 microliters in these wells.

(3) Transfer each serum sample as described in § 147.5(d)(2) of this section to the first well containing 100 microliters (0.10cc.) in the titration, which represents the lowest dilution.

(4) Make two-fold serial dilutions of each serum by transferring 50 microliters (0.05cc.) of diluted serum from one well to the next using twelve 50 microliter microdiluters fitted in a multimicrodiluter handle. When transfers have been made to all of the wells of the desired series, the 50 microliters remaining in the microdiluters are removed by blotting, touching the microdiluters to the surface of the distilled water wash, and blotting again.

(5) Dilute the desired microtest antigen with 0.50 percent phenolized saline and add 50 microliters (0.05 cc.) to each microplate well.

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[1] Information as to criteria and procedures for approval of concentrated stock suspension of stained microtest antigens may be obtained from the National Poultry Improvement Plan Staff, Building 265, Beltsville Agricultural Research Center-East, Beltsville, Maryland 20705.

(6) Seal each plate with a plastic sealer or place the unsealed microplates in a tight incubation box and incubate at 37° C. for 18-24 hours.

(7) Read the test results as described in paragraph (f) of this section.

(f) Read the test results with the aid of a reading mirror. Results are interpreted as follows:

(1) N, or – (negative) when the microplate well has a large, distinct button of stained cells; or

(2) P, or + (positive) when the microplate well reveals no antigen button; or

(3) S, or ? (suspicious) when the microplate well has a small button. Suspicious reactions may tend to be more positive than negative [±] or vice versa [±] and can be so noted if desired.

[41 FR 48726, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 147.6 Procedure for determining the status of flocks reacting to tests for Mycoplasma gallisepticum, Mycoplasma synoviae, and Mycoplasma meleagridis.

The macroagglutination tests for Mycoplasma antibodies, as described in "Standard Methods for Testing Avian Sera for the Presence of Mycoplasma Gallisepticum Antibodies" published by the Agricultural Research Service, USDA, March 1966, and the microagglutination tests, as reported in the Proceedings, Sixteenth Annual Meeting of the American Association of Veterinary Laboratory Diagnosticians, 1973, shall be the official tests. Procedures for isolation and identification of Mycoplasma may be found in Isolation and Identification of Avian Pathogens, published by the American Association of Avian Pathologists and §§ 147.15 and 147.16 of this part.

(a) When reactors are submitted to a laboratory as prescribed by the Official State Agency, the following criteria shall be used to determine if the flock is positive for M. gallisepticum, M. synoviae, or M. meleagridis:

(1) Active air sac lesions, sinusitis, synovitis, or other clinical signs of a respiratory disease;

(2) Recovery by culture of the Mycoplasma for which the flock was tested;

(3) Supplemental serological test.

(b) If all of these tests are negative, the flock shall be deemed to have had no reactors for the Mycoplasma for which the flock was tested. If the Mycoplasma for which the flock was tested is isolated bacteriologically, the flock shall be considered infected. If any of the other tests described in paragraphs (a) (1) or (3) of this section is positive, the flock shall be considered suspicious, and additional agglutination and hemagglutination inhibition (HI) tests shall be conducted according to the following sequence:

(1) If the tube agglutination or the serum plate test is negative, the flock qualifies.

(2) If the tube agglutination or the serum plate test is positive, the hemaglutination inhibition (HI) test and/or the Serum Plate Dilution (SPD) test shall be conducted.

(3) If the tube agglutination or serum plate tests are positive and HI and/or the SPD tests are negative, the flock shall be retested in accordance with paragraph (b)(6) of this section.

(4) If HI titers of 1:40 or SPD titers of 1:5 are found, the flock shall be considered suspicious and shall be retested in accordance with paragraph (b)(6) of this section.

(5) If HI titers of 1:80 or SPD titers of 1:10 or higher are found, the flock shall be considered infected: *Provided*, That, at the discretion of the Official State Agency, additional tests may be conducted in accordance with (b)(6) of this section before final determination of the flock status is made.

(6) Fourteen days after the previous bleeding date, all birds or a random sample comprised of 75 birds shall be tested by the serum plate or tube agglutination test. Tested birds shall be identified by numbered bands.

(7) If the tube agglutination test or serum plate test is negative for the Mycoplasma for which the flock was tested, the flock qualifies.

(8) If the tube agglutination or serum plate test is positive, the HI and/or SPD test shall be conducted on the reacting samples.

(9) On the retest, if the tube agglutination or serum plate tests are positive at the same or higher rate and the HI or SPD tests are negative, the flock

shall be considered suspicious and shall be retested in accordance with paragraph (b)(6) of this section.

(10) On the retest if HI titers of 1:80 and/or SPD titers of 1:10 or higher are found, the flock shall be considered infected: *Provided*, That, at the discretion of the Official State Agency, additional tests may be conducted in accordance with paragraph (b)(6) of this section before final determination of the flock status is made.

(11) If HI titers of 1:80 and/or SPD titers of 1:10 or higher are found on the second retest, the flock shall be considered infected for the Mycoplasma for which it was tested.

(12) If the tube agglutination or serum plate tests are found on the second retest to be positive at the same or higher rate and the HI and/or SPD tests are negative, the flock should be considered infected: *Provided*, That if the status of the flock is considered to be equivocal, the Official State Agency may examine reactors by the in vivo bio-assay and/or culture procedures before final determination of the flock status is made.

(13) If the in vivo bio-assay and culture procedures are both negative, the Official State Agency may qualify the flock for the classification for which it was tested.

(14) If the in vivo bio-assay or culture procedures are positive, the flock shall be considered infected: *Provided*, That if only the bio-assay is positive, additional in vivo bio-assay or cultural examinations may be conducted by the Official State Agency before final determination of the flock status is made.

(15) If the in vivo bio-assay or cultures are positive on retest, the flock shall be considered infected for the mycoplasma for which it was tested.

[40 FR 1504, Jan. 8, 1975, as amended at 41 FR 48726, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 47 FR 21993, May 20, 1982; 50 FR 19900, May 13, 1985]

§ 147.7 Standard test procedures for mycoplasma.[1]

The serum plate of the tube agglutination test should be considered basic screening tests for mycoplasma antibodies. The test selected will depend on preference, laboratory facilities, and availability of antigen. Both tests, though quite accurate, determine flock status rather than individual bird status, since occasional reactions are nonspecific. Under normal circumstances, the rate of such nonspecific reactions is low. Nonspecific reactions may occasionally be high, particularly after the use of erysipelas bacterin in turkeys and where mycoplasma antibodies are present for closely related mycoplasma other than for the species being tested. The hemagglutination inhibition (HI) test is too cumbersome for routine screening use. Positive reactions are extremely accurate however, and are useful in evaluating serum samples that react with the plate any/or tube antigens. The test should be conducted with 4 HA units. Titers of 1:80 or greater for both chicken and turkey sera are considered positive, while a 1:40 or 1:20 titer would be strongly suspicious and additional tests should be required.

(a) *Serum plate test.* (1) The serum plate test for mycoplasma is conducted by contacting and mixing 0.02 ml of test serum with 0.03 ml of serum plate antigen on a glass at room temperature. The standard procedure is:

(i) Allow antigen and test serums to warm up to room temperature before use.

(ii) Dispense test serums in 0.02 ml amounts with a pipette or standardized loop (rinsed between samples) to 1½ inch squares on a ruled glass plate. Limit the number of samples (no more than 25) to be set up at one time according to the speed of the operator. Serum should not dry out before being mixed with antigen.

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[1] For additional information on mycoplasma test procedures, refer to the following references: Proc. 77th Annual Meeting, U.S. Animal Health Association, 1973; Isolation and Identification of Avian Pathogens, 2nd Edition; Methods for Examining Poultry Biologics and for Identifying and Quantifying Avian Pathogens, 1971.

(iii) Dispense 0.03 ml of antigen beside the test serum on each square. Hold antigen dispensing bottle vertically.

(iv) Mix the serum and antigen, using a multimixing device if large numbers are to be run at one time.

(v) Rotate the plate for 5 seconds. At the end of the first minute, rotate the plate again for 5 seconds and read 55 seconds later.

(2) A positive reaction is characterized by the formation of definite clumps, usually starting at the periphery of the mixture. Most samples that are highly positive will react well within the 2-minute test period. Reactions thereafter should be considered negative, although partial agglutination at 3 and 5 minutes may warrant further retesting. High-quality antigen contacted with negative serum will usually dry up on the plate without visible clumping. Whenever samples are run, the antigen should be tested against known positive and negative control serums. Standard reference antigens and negative and positive titered sera are available from the National Veterinary Services Laboratories (NVSL), P.O. Box 884, Ames, Iowa 50010.

(3) Since it is difficult to measure uniform amounts of serum with a calibrated loop, this technique should not be used in conducting an official test.

(b) *Serum plate dilution test.* (1) The serum plate dilution (SPD) test may be used to evaluate possible nonspecific reactions, gain additional information to evaluate positive plate tests occurring in an unexpected manner, and/or to evaluate the level of mycoplasma antibodies present in the serum sample. If sufficient serum is available, the following method would provide the dilutions required to conduct the test.

(i) Rack three tubes and put 0.8 ml of phosphate-buffered saline (PBS) in tube 1 and 0.5 ml of PBS in tubes 2 and 3.

(ii) Pipette 0.2 ml of the test serum into tube 1 and discard the pipette.

(iii) With a pipette, mix the serum and PBS in tube 1 and withdraw 0.5 ml and add to tube 2.

(iv) Repeat the process in step (iii), mixing the contents of tube 2 and transferring 0.5 ml to tube 3.

(v) Conduct the test, as described for the serum plate test in paragraph (a), on the undiluted sample and on samples in tubes 1, 2, and 3 after proper mixing of each dilution.

(vi) To assist in the evaluation of the test, conduct concurrent SPD tests using both positive 1:80 and positive 1:160 HI sera for the mycoplasma being tested. The antigen should be pretested for reactivity with standard serum at the 1:5 and 1:10 dilution.

(vii) Interpretation of the SPD test results should be based on the criteria in § 147.6(b) of this part.

(c) *Tube agglutination test.* (1) The mycoplasma tube agglutination test is conducted by mixing 0.08 ml of test serum with 1.0 ml of diluted (1:20) antigen in a tube and allowing the mixture to react for 18–24 hours at 37°C. The diluent will be the standard phosphate-buffered saline with phenol. This solution is made up as follows:

	Grams
Sodium hydroxide (C.P.)	0.15
Sodium chloride (C.P.)	8.5
Potassium dihydrogen phosphate (KH_2PO_4) (C.P.)	0.68
Phenol (Crystal) (C.P.)	2.5
Distilled water to make 1,000 ml	

The pH of the buffered phenolized saline will be 7.1–7.2 if all reagents are accurately measured. The stock tube antigen is diluted 1:20 with buffered phenolized saline. The procedures for the tube test are as follows:

(i) Rack 12 x 75 mm clean tubes and identify the tubes according to the sample to be tested.

(ii) Add 0.08 ml of the individual test serum to each tube. This will create approximately a 1:12.5 screening dilution of test serum when 1.0 ml of diluted antigen is added. The use of a pipetting device will insure proper mixing of serum and antigen.

(iii) To interpret positive reactions to the 1:12.5 dilution, two additional dilutions may be made by adding 0.04 ml of serum for 1:25 dilution and 0.02 ml of serum for 1:50 dilution, with the addition of 1.0 ml of diluted antigen as indicated in paragraph (c)(1)(ii) above.

(iv) Shake racks and incubate test systems for 18-24 hours at 37°C.

(2) Tests are read against a dark background under indirect fluorescent light. Regarded as a positive reaction is a clearing of the supernatant fluid, with visible sediment in the bottom of the tube. Incomplete reactions are suspect. Positive and negative control serums should be incorporated into each day's run of tests. Reactions at 1:25 or greater are considered positive. They should be confirmed by the HI test. Incubation for periods greater than 24 hours may be helpful in evaluating suspicious reactions and need for possible retesting or other diagnostic tests.

(d) *Hemagglutination Inhibition (HI) test.* The mycoplasma HI test is conducted by the constant-antigen, decreasing-serum method. This method requires using a 4-hemagglutination (HA) unit of diluted antigen. Differences in the number of HA units used will change the titers of positive sera markedly. Standard HA antigens for *Mycoplasma gallisepticum, M. synoviae,* and *M. meleagridis* are available from NVSL. The antigen has been titrated and diluted to approximately 1:640. The HA titration of each sample should be checked as described in paragraph (d)(2) on initial use or after long storage. To maintain HA activity, the undiluted HA antigen should be stored at −60° to −70°C. The test procedures are illustrated in Tables 2 and 3 of this paragraph.

(1) *Preparation of materials.*

(i) Prepare phosphate-buffered saline (PBS) as follows:

	Grams
Sodium hydroxide (C.P.)	0.15
Sodium chloride (C.P.)	8.5
Potassium dihydrogen phosphate (KH_2PO_4) (C.P.)	0.68
Distilled water to make 1,000 ml	

The pH of the PBS will be 7.1-7.2 if all reagents are accurately measured.

(ii) Collect the turkey or chicken red blood cells (RBC's) in Alsever's solution which has been prepared as follows:

	Grams
Sodium citrate	12.0
Sodium chloride	4.2
Dextrose	20.5

The sodium citrate and sodium chloride are dissolved in 800 ml distilled water and sterilized at 15 lbs. pressure for 15 minutes. Dissolve the dextrose in 200 ml distilled water, sterilize by Seitz or other type of filtration and then add aseptically to the sterile sodium citrate and sodium chloride solution.

(iii) From a turkey(s) or chicken(s) known to be free of the mycoplasma being tested, withdraw sufficient blood with a syringe containing Alsever's solution to give a ratio of 1 part blood to 5 parts Alsever's solution (e.g., 8 ml blood in 40 ml of Alsever's solution). Centrifuge the blood suspension at 1,000 rpm for 10 minutes and remove the Alsever's solution or supernatant with a pipette.

(iv) Wash the RBC's two times in 10 or more parts of Alsever's solution, centrifuging after each washing. Centrifugation is at 1,000 rpm for 10 minutes. The supernatant fluid is removed and the RBC deposit resuspended to give a 25 percent suspension of packed RBC's in Alsever's solution. (In testing either chicken or turkey sera, the homologous RBC system must be used; i.e., use chicken cells when testing chicken serum and turkey cells when testing turkey serum.) If this suspension is kept refrigerated, it should keep for 7 or 8 days after the blood has been collected.

(v) For the test, 1 ml of the 25 percent RBC's is added to 99 ml of buffered saline to make a 0.25 percent RBC suspension.

(2) *Hemagglutination (HA) antigen titration.* The HA stock antigen is stored at −70 °C in PBC buffer containing 25 percent glycerin (vol/vol) in a concentrated suspension (i.e., 320-640 HA units/ml) in screwtype vials. Under such conditions, potency will be retained for years. There will be a rapid loss of titer if improperly stored. The titer of HA antigen is determined as illustrated in Table 1 and described in subparagraphs (d)(2) (i) thru (x) of this paragraph.

TABLE 1 Titration of Hemagglutination (HA) Antigen

			Tube No.			
Reagents (ml)	1	2	3 8	9	10	11[a]
PBS	0.8	0.5	0.5.........0.5	0.5	0.5	0.5
Antigen	0.2					
Transfer	0.5→	0.5→	0.5—...→ 0.5→	0.5→	0.5↓[c]	
0.25% RBC	0.5	0.5	0.5 .... 0.5	0.5	0.5	0.5
Ant. dilution	1:5	1:10	1:20 ...... 1:640	1:1280	1:2560	
Results[b]	+	+	+ ...... +	-	-	

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[a] Tube 11, PBS/RBC control.

[b] + = HA; - = no HA (sample titer 1:640).

[c] Discard 0.5 ml.

(i) Rack a series of 11 chemically clean 12 x 75 mm test tubes. Label the tubes 1-11 left to right.

(ii) Put 0.8 ml of PBS in tube 1 and 0.5 ml of PBS in each of tubes 2-11.

(iii) Add 0.2 ml of antigen to tube 1. This will make a 1:5 dilution of antigen. Discard pipette.

(iv) Mix contents of tube 1 thoroughly with a clean pipette, and transfer 0.5 ml to tube 2. This will make a 1:10 dilution of antigen in tube 2. Discard pipette.

(v) Continue making serial twofold dilutions of antigen, changing pipettes after each transfer, through tube 10. This will result in a series of twofold dilutions ranging from 1:5 to 1:2560. Discard 0.5 ml of antigen dilution from tube 10.

(vi) Add 0.5 ,ml of 0.25 percent RBC's to tubes 1-11. Tube 11 will serve as PBS/RBC control.

(vii) Shake the rack and incubate at room temperature until the cells in the PBS/RBC control tube have settled into a compact button at the bottom of the tube.

(viii) If turkey sera is also to be tested for HI titer, repeat steps outlined in (d)(2) (i) thru (vii) of this paragraph, using 0.25 percent turkey RBC's.

(ix) The end point of the titration is the highest dilution of antigen that produces complete agglutination of the RBC's, as evidenced by the formation of a thin sheet of cells covering the concave bottom of the tube. For example, if complete agglutination is produced through tube 8 (a dilution of 1:640 of antigen), the antigen would be said to titer 640, the reciprocal of the dilution.

(x) Specificity of HA antigen should be determined by conducting HI tests with specific chicken sera of variable HI titers. Specific turkey sera of varying HI titers should be used if turkey sera is also to be tested.

TABLE 2 Hemagglutination Inhibition (HI) Test:

	Tube No.						
Reagents (ml)	1[a]	2	3	8	9	10	11[b]
PBS	0.8	0	0		0	0	0.5
8-unit antigen	0	0.5	0		0	0	0
4-unit antigen	0	0	0.5	0.5	0.5	0.5	0
Test serum	0.2	0	0	0	0	0	0
Transfer	0.5→	0.5→	0.5—...→	0.5→	0.5→	0.5↓[c]	
0.25% RBC	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Serum dilution	1:5	1:10	1:20 ...	1:640	1:1280	1:2560	

[a] Tube 1. Serum control.

[b] Tube 11. PBS/RBC control.

[c] Discard 0.5 ml.

TABLE 3 Antigen Control:

	Tube No.				
Reagents (ml)	1	2	3	4	5
4-unit antigen	1.0	0	0	0	0
PBS	0	0.5	0.5	0.5	0.5
Transfer	0.5→	0.5→	0.5→	0.5→	0.5[b]↓
0.25% RBC	0.5	0.5	0.5	0.5	0.5
Unit Antigen/tube	4	2	1	1/2	1/4
Results[a]	+	+	+	-	-

[a] + = HA; - = no HA.

[b] Discard 0.5 ml.

(3) *Reagents for mycoplasma HI test.*

(i) Eight-unit antigen (Dilution factor for stock antigen is established by dividing titer by 8; i.e., 640 antigen is diluted 1:80 in PBS to make 8-unit antigen.)

(ii) Four-unit antigen (made by diluting surplus 8-unit antigen 1:2 with PBS).

(iii) PBS at pH 7.0.

(iv) Unknown test serums.

(v) Positive control serum of known titer (should be from the same species as the unknown).

(vi) Negative control serum (should be from the same species as the unknown).

(vii) Solution of 0.25 percent washed RBC's.

(4) *Test outline.*

(i) Rack 10 chemically clean 12 x 75 mm tubes for each serum, including controls, to be tested. Identify each row of tubes, and label tubes in each row 1–10, left to right. In row 1, add tube 11 for a PBS/RBC control.

(ii) Put 0.8 ml of PBS in tube 1 of each test row; put 0.5 ml of 8-unit antigen in tube 2 of each test row; put 0.5 ml of 4-unit antigen in each of tubes 3–10 in each test row; and put 0.5 ml of PBS in tube 11.

(iii) Add 0.2 ml of test serum to tube 1. This tube will be the serum control in the test system.

(iv) Mix and make 0.5 ml transfers from tube 1 through tube 10. This will result in serial twofold dilutions of serum starting with 1:5 and ending with 1:2560. Discard 0.5 ml from tube 10.

(v) Rack five tubes in which to set up an antigen control.

(vi) In tube 1, put 1.0 ml of 4-unit antigen; put 0.5 ml of PBS in tubes 2–5.

(vii) Make 0.5 ml serial transfers from tube 1 through tube 5, changing pipettes after each transfer. Discard 0.5 ml from tube 5. This will result in a series of tubes respectively containing 4, 2, 1, ½, and ¼ units of antigen.

(viii) After 20–30 minutes at room temperature to permit antibody-antigen reaction, add 0.5 ml of 0.25 percent washed RBC's to each tube. Shake racks and incubate as for HA titration.

(ix) In this test system, positive serum should inhibit the HA activity of the antigen, while negative serum should have no effect. Inhibition will be evidenced by the formation of a free-flowing button of cells in the botton of the tube. The titer of the serum can be calculated as the reciprocal of the highest dilution of serum that produces complete HI. Controls should read as follows:

(A) Serum control (tube 1). Cells should settle out.

(B) PBS/RBC control (tube 11). Cells should settle out.

(C) Antigen control. HA in tubes 1–3. Cells should settle out in tubes 4–5.

(D) Positive and negative serum control. Positive control should inhibit to its known titer; negative control should have no inhibitory effect.

(x) With this test system and 4 units of antigen, HI titers of 80 or above are considered positive and titers of 40 are strongly suspicious. However, titers of 10 or 20 are usually negative. Sample test results are illustrated in Table 4 in this paragraph.

TABLE 4.—SAMPLE RESULTS OF HI TESTS

[Tube and Serum Dilution]

	1	2	3	4	5	6	7	8	9	10
	1.5	1:10	1:20	1:40	1:80	1:160	1:320	1:640	1:1280	1:2560
Serum A (HI neg.)	−	+	+	+	+	+	+	+	+	+
Serum B (HI 1:40)	−	−	−	−	+	+	+	+	+	+
Serum C (HI 1:160)	−	−	−	−	−	−	+	+	+	+
Serum D (HI 1:20)	−	−	−	+	+	+	+	+	+	+

+, HA.
−, no HA or HI.

(xi) If serological results from agglutination tests complemented by the HI test are inconclusive, cultural examination, bio-assay, or retesting of samples after an interval of at least 21 days may be indicated.

(e) *Procedure for mycoplasma hemagglutination inhibition test using microtiter technique.* The microtiter mycoplasma HI test was developed from the tube HI test described in § 147.7(c). Refer to these procedures for preparation of materials not listed below.

(1) *Materials needed.* (i) Microtiter equipment (minimal); i.e., microplates, microdiluters, micropipettes, go-no-go diluter delivery tester, (0.05 ml).

(ii) Phosphate-buffered saline (PBS).

(iii) Reagents from NVSL; i.e., HA antigen and negative and positive titered sera for the mycoplasma to be tested.

(iv) Homologous red blood cells (RBC's) suspension 0.5 percent (2 ml of 25 percent RBC's to 98 ml of PBS) obtained from birds free of the mycoplasma to be tested. (See paragraph (d)(1)(iv) of this section for preparation of RBC's.)

(2) *Microtiter hemagglutination (HA) antigen titration.* (i) Mark off two rows of 10 wells each for antigen titer (HA is done in duplicate).

(ii) Mark last well in each row for cell controls.

(iii) Prepare in small test tube (12 x 75 mm) a starting dilution of antigen by combining 0.1 ml antigen with 0.9 ml PBS. This is a 1:10 dilution.

(iv) Add 0.05 ml PBS to all wells, including cell controls.

(v) Add 0.05 ml antigen (1:10 dilution) with diluters to the first well in both rows, mix thoroughly, transfer diluter to second well of each row and mix, continuing through the 10th well of each row. With mixture in diluter from last well, check diluter on go-no-go card, then place diluter in distilled water. If diluter checks out, antigen dilution will be 1:20, 1:40, 1:80, 1:160, 1:320, 1:640, 1:1280, 1:2560, 1:5120.

(vi) Add 0.05 ml of 0.5 percent RBC suspension to all wells using a 0.05 dropper.

(vii) Seal plate (if plate is to be held over 2 hours); shake and allow to stand at room temperature until cells in cell control gather in compact button. The titer is the highest dilution in which agglutination is complete. The dilution contains 1 HA unit in 0.05 ml.

(viii) Prepare a dilution of antigen which contains 8 HA units in 0.05 ml. Example: if the antigen titer is 1:640, then that dilution contains 1 HA unit per 0.05 ml. Then 640÷8=80, or a dilution of 1:80 containing 8 HA units. Or 640÷4=160, a dilution of 1:160 containing 4 HA units per 0.05 ml.

(3) *Microtiter HI test.* (i) Prepare two dilutions of antigen, one containing 8 HA units per 0.05 ml and one containing 4 HA units per 0.05 ml. The 4-unit antigen can be prepared from the 8-unit antigen by mixing with equal parts of PBS.

(ii) Mark off one row of 8 wells for each test.

(iii) Prepare a 1:5 dilution of each sera to be tested in a small test tube (12×75 mm): 0.1 ml serum plus 0.4 ml PBS or 0.05 ml serum plus 0.20 ml PBS.

(iv) Add 0.05 ml PBS with the 0.05 ml dropper to the first well in each row.

(v) Add 0.05 ml of 8-unit antigen to well 2 in each row.

(vi) Add 0.05 ml of 4-unit antigen to well 3 through 8 for each row.

(vii) For each serum to be tested, load 0.05 ml diluter with 1:5 dilution as prepared in paragraph (iii) above and place in first well of row.

(viii) Mix well and transfer loaded diluter to well 2. Continue serial twofold dilutions through well number 8.

(ix) Well 1 (serum dilution of 1:10) is serum control. Well 2=1:20 dilution; well 3=1:40 dilution; well 4=1:80 dilution; well 5=1:160 dilution; well 6=1:320 dilution; well 7=1:640 dilution; and well 8=1:1280 dilution.

(x) *Antigen control.* (A) Mark off 6 wells for antigen controls.

(B) Add 0.05 ml PBS to wells 2, 3, 4, 5, and 6.

(C) Add 0.05 ml 8-unit antigen to wells 1 and 2.

(D) With empty diluter, mix contents of well 2. Continue serial twofold dilutions through well 6.

(E) Well 1 contains 8 units; well 2 contains 4 units; well 3 contains 2 units; well 4 contains 1 unit; well 5 contains ½ unit; and well 6 contains ¼ unit.

(F) Mark off two wells for cell controls and add 0.05 ml PBS to each.

(G) After 20–30 minutes at average room temperature (20°–23°C) to permit antibody-antigen reaction, add 0.05 ml of a 0.05 percent suspension of RBC's to all wells.

(H) Seal all wells (if wells are to be held over 2 hours). Shake the plate thoroughly.

(I) Incubate at room temperature for 30–45 minutes.

(xi) *Interpretation:* The HI titer is the highest serum dilution exhibiting complete inhibition of hemmagglutination as indicated by flowing of cells when the plate is tilted. Serum having a titer of 1:80 or greater is considered positive. A titer of 1:40 or 1:20 is suspicious.

[49 FR 19803, May 10, 1984]

§ 147.8 Procedures for preparing egg yolk samples for diagnostic tests.

The following testing provisions may be used for retaining the classification U.S. M. Gallisepticum Clean under § 145.23(c)(1)(ii)(C) and § 145.33(c)(1)(ii)(C), and for retaining the classification U.S. M. Synoviae Clean under § 145.23(e)(1)(ii)(*b*) and § 145.33(e)(1)(ii)(*b*).

(a) Under the supervision of an Authorized Agent or State Inspector, the eggs which are used in egg yolk testing must be selected from the premises where the breeding flock is located, must include a representative sample of 30 eggs collected from a single day's production from the flock, must be identified as to flock of origin and pen, and must be delivered to an authorized laboratory for preparation for diagnostic testing.

(b) The authorized laboratory must identify each egg as to the breeding flock and pen from which it originated, and maintain this identity through each of the following:

(1) Crack the egg on the round end with a blunt instrument.

(2) Place the contents of the egg in an open dish (or a receptacle to expose the yolk) and prick the yolk with a needle

(3) Using a 1 ml syringe without a needle, aspirate 0.5 ml of egg yolk from the opening in the yolk.

(4) Dispense the yolk material in a tube. Aspirate and dispense 0.5 ml of PBS (phosphate-buffered saline) into the same tube, and place in a rack.

(5) After all the eggs are sampled, place the rack of tubes on a vortex shaker for 30 seconds.

(6) Centrifuge the samples at 2500 RPM (1000 x g) for 30 minutes.

(7) Test the resultant supernatant for *M. gallisepticum* and *M. synoviae* by using test procedures specified for detecting IgG antibodies set forth for testing serum in § 147.7 (for these tests the resultant supernatant would be substituted for serum); except that a single 1:20 dilution hemagglutination inhibition (HI) test may be used as a screening test in accordance with the procedures set forth in § 147.7.

NOTE.—For evaluating the test results of any egg yolk test, it should be remembered that a 1:2 dilution of the yolk in saline was made of the original specimen.

[50 FR 19900, May 13, 1985]

Subpart B—Bacteriological Examination Procedure

§ 147.11 Laboratory procedure recommended for the bacteriological examination of salmonella reactors.

(a) Grossly normal or diseased liver, heart, pericardial sac, spleen, lung, kidney, pancreas, peritoneum, drained gall-bladder, oviduct, misshapen ova, testes, inflamed or unabsorbed yolk sac, and other visibly pathological tissues where purulent, necrotic, or proliferative lesions are seen (including cysts, abscesses, hypopyon, and inflamed serosal surfaces), should be directly cultured by means of a flamed wire loop or with sterile swabs.[1] Careful aseptic technique must be utilized throughout the process of collecting tissues. Selective media should not be relied upon to deal with contaminants, since some strains may not dependably survive and grow in certain selective media. Inoculate veal infusion (VI) and brilliant green (BG) agar plates. Incubate the plates for 24 and 48 hours at 37°C. The digestive system should always be cultured separately (see paragraph (f) of this section) after other anatomical organs and systems have been collected and cultured.

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[1] Culture media preparation and biochemical identification charts can be obtained from *Culture Methods for the Detection of Animal Salmonellosis and Arizonosis*, Committee on Salmonellosis and Arizonosis, AAVLD, 1976 Iowa State University Press, Ames, IA 50010.

(b) The following organs should be aseptically collected for culture:

(1) Heart (apex, pericardial sac, and contents if present.);

(2) Liver (portions exhibiting lesions or, in grossly normal organs, the drained gall bladder and adjacent liver tissues.);

(3) Ovary-Testes (entire inactive ovary or testes, but if ovary is active, use own judgment and include any atypical ova.);

(4) Oviduct (if active, include any debris and dehydrated ova.);

(5) Pancreas and kidneys; and

(6) Spleen.

(c) Aseptically collect 10–15 g or whatever lesser amount is available of each organ or site listed in paragraph (b) from each reactor, and grind or blend them completely in 10 times their volume of VI broth. Organs may be processed individually or in combinations where appropriate. Suspensions should be transferred in 10-ml aliquots to 100-ml of both VI and tetrathionate brilliant green (TBG) broth and incubated at 37°C for 24 hours. Plate the VI broth on VI and BG agar and plate the TBG broth on BG agar and incubate at 37°C. Examine these plates after 24 and 48 hours of incubation. The contents of the gallbladder can be cultured separately by inoculating 10-ml of VI and TBG broth with cotton swabs and incubating at 37°C for 24 hours. Plate on BG agar and incubate at 37°C. Examine these plates after 24 and 48 hours of incubation. If contamination with pseudomonas or proteus is a problem, make platings on BG sulfapyridine (BGS) agar.

(d) Where field samples are directly inoculated into enrichment broths and a delay of several days occurs before they reach a laboratory, or if recovery of low numbers or organisms is expected from a primary culture, a secondary enrichment culture should be prepared. Subculture a week-old primary culture by transferring 1-ml of inoculum into a fresh tube 10-ml of enrichment broth. This secondary enrichment should be incubated at 37°C for 24 hours before plating. (See paragraph (a) of this section.) TBG broth is recommended for this procedure.

(e) Make a composite sample of the following parts of grossly normal or diseased tissues from the digestive tract: Crop wall, duodenum, jejunum (including remnant of yolk-sac attachment), both ceca, cecal tonsils, and rectum-cloaca. Aspetically collect 10-15 g of each organ or tissue, or whatever lesser amount is available, and grind or blend them completely in 10 times their volume of TBG broth. Transfer 10-ml of a composite sample of a suspension from the digestive tract into 100-ml of TBG broth, and incubate flasks at 42°C for 24 hours. Cultures may be incubated at 37°C if 42°C incubators are not available. The higher incubation temperatures for TBG broth reduce populations of competitive contaminants common in gut tissue. Plate on BG agar and incubate at 37°C. Examine the plates after 24 and 48 hours of incubation. If contamination with pseudomonas or proteus is a problem make platings on BGS agar.

(f) If preferred, individual cotton swab samples may also be taken from the upper, middle, and lower intestinal tract (including both ceca and the rectum-cloaca). Deposit swabs in 10-ml of TBG broth and incubate and plate as described in paragraph (e) of this section.

(g) Transfer suspect colonies to triple-sugar-iron (TSI) agar and lysine-iron (LI) agar and incubate at 37°C for 24 hours.

(h) Cultures revealing typical reactions of salmonellae on TSI and LI agar slants should be transferred to any of the following appropriate biochemical tests for final identification: Dextrose, lactose, sucrose, mannitol maltose, dulcitol, malonate, gelatin, urea broth, citrate, lysine decarboxylase, ornithine decarboxylase, methyl red and Voges-Proskauer, KCN, salicin broths, indole, and hydrogen sulfide. Motility or non-motility is demonstrated by inoculating a suitable semisolid medium.[2] The Analytical Profile Index for Enterobacteriacae (API) system may be utilized for identification if feasible. For arizonae identification, make readings daily up to 10 days. An O-nitrophenyl-beta-D-galactopyranside (ONPG) disc may be used to identify slow lactose fermenters.[3]

(i) All salmonella cultures should be serologically typed.

[36 FR 23121, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 47 FR 21994, May 20, 1982; 50 FR 19900, May 13, 1985]

§ 147.12 Procedures for collecting environmental samples and cloacal swabs for bacteriological examination.

Information concerning the pen arrangement and number of birds per pen should be obtained from the owner so that the required number of samples per pen and per flock can be determined. A means of identifying each sample by pen of origin should be provided. The vehicle transporting the personnel taking the samples should be left as far as practical from the poultry pens. Sanitary precautions, including personal cleanliness, should be observed during the sampling procedure. The hands should be carefully washed with a sanitizing soap prior to the sampling. Outer clothing, including gloves, should be changed between visits to different premises so that clean clothing is worn upon entering each premises.

The used and clean apparel should be kept separate. Boots or footwear should be cleaned and disinfected between visits to different premises. Disposable caps should be provided and discarded after use on each premises. After collection, the samples should be protected from drying, light, and excessive temperatures and delivered to the laboratory within one day. If delivery is delayed, samples should be refrigerated.

(a) *Environmental samples.* Fecal material, litter, or dust to be submitted for bacteriological examination should be collected in accordance with the procedures described in paragraphs (a)(1) or (2) of this section:

(1) *Procedure for sampling in broth.* Authorized laboratories will provide capped tubes 1-2 cm in diameter and 15-20 cm in length which are two-thirds full of a recently made, refrigerated, sterile enrichment broth (Selenite Brilliant Green Sulfapyridine or Tetrathionate Brilliant Green) for each sample. Sufficient tubes should be taken to the premises to provide at least one tube per pen or one tube per 500 birds, whichever is greater. At least one sterile, cotton-tipped applicator will be needed for each tube. The dry applicator is first placed or drawn through fresh manure (under roost, near water troughs, cecal droppings, or diarrhetic droppings). After this and each subsequent streaking, the cotton-tipped applicator is placed in the tube of broth and swirled to remove the collected material. The applicator is then withdrawn and is used for taking additional specimens by streaking on or through areas where defecation, trampling of feces, or settling of dust are common; i.e., on or near waterers, feeders, nests, or rafters, etc. When the volume of material collected equals approximately 10 percent of the volume of the broth (usually 10-12 streakings), the applicator is placed in the tube and the stick is broken in half. The lower or cotton-tipped half is left in the broth, and the upper half is retained for future disposal. The cap is then replaced on the inoculated tube, and the sampling procedure is continued in other areas of the pen.

(2) *Procedure for sampling in dry containers.* A sample of fecal material, litter, or dust is placed in a sterile, sealable container. The sample shall consist of several specimens of material taken from a representative location

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[2] Formulation for the semisolid motility medium can be obtained from: *Isolation and Identification of Avian Pathogens*, American Association of Avian Pathologists, Texas A&M University, College Station, TX 77843, 1980.

[3] ONPG discs are available from: Baltimore Biological Laboratories, Cockeysville, MD 21030.

in the pen. At least 10 g (approximately a heaping tablespoonful) of material shall be collected for each sample. The specimens in each sample shall be collected with a sterile tongue depressor or similar uncontaminated instrument. The samples should vary in type and consistency. Half of the samples should be comprised of material representing defecated matter from a large portion of the flock; i.e., trampled, caked material near waterers and feeders. The minimum number of samples to be taken shall be determined by the following:

Five samples from pens of up to 500 birds;
Ten samples from pens of 500 to 2,500 birds;
Fifteen samples from pens with more than 2,500 birds.

(b) *Cloacal swabs.* Cloacal swabs for bacteriological examination are taken from each bird in the flock or from a minimum of 500 birds in accordance with the procedure described in paragraph (a)(1) of this section.

(1) *Procedure for taking cloacal swabs.* The authorized laboratory will provide sterile capped tubes or other suitable containers and cotton-tipped applicators for use in taking the cloacal swabs. The cotton-tipped applicator is inserted into the cloaca and rectum in such a manner as to insure the collection of fecal material. The swab and adhering fecal material is then placed in the tube and the stick is broken in half, with the upper half retained for future disposal. The cloacal swabs may be combined in the sterile tubes in multiples of five or in combinations specified by the authorized laboratory.

[38 FR 13709, May 24, 1973. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 147.13 Procedure for bacteriological culturing of eggshells for colon bacilli organisms.

Proper precautions to avoid environmental contamination of the samples during the collection and laboratory process, and proper handling of the samples following collection are essential. Each State Inspector involved in eggshell culture activities must receive instruction in the necessary sanitation procedures, sampling procedures, and sample handling by the authorized laboratory involved. The Official State Agency will maintain a record showing that the required instruction was given to each State Inspector.

(a) *Sample selection.* Forty (40) eggs in the top flats of each of three randomly selected cases of sanitized eggs from each flock will be utilized for each sampling.

(b) *Swab procedure.* A 2.5 centimeter diameter circular area of the large end of each of the eggs will be rubbed with a sterile swab previously moistened with sterile lactose broth, or other suitable liquid media provided by the authorized laboratory. One swab will be used for five eggs, and four swabs will be pooled to each sterile, capped tube provided by the authorized laboratory.

(1) From the tube containing four swabs and lactose broth or other suitable media, 1 ml. will be transferred to 10 ml. lactose in a fermentation tube.

(2) Incubate at 37° C for 48 hours. The presence of acid, and gas in the amount of 10 percent or more after 24 and 48 hours of incubation, provides a presumptive conclusion of the presence of colon bacilli organisms.

[41 FR 14256, Apr. 2, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 147.14 Procedures to determine status and effectiveness of sanitation monitored program.[1]

The following monitoring procedures may be applied at the discretion of the Official State Agency:

(a) Monitor effectiveness of sanitation program.

(1) Culture the surface of cased eggs periodically for fecal contaminating organisms as described in § 147.13.

(2) Culture a sample of dead-in-shell eggs periodically from each breeding flock for coliforms. The culture media

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[1] Laboratory procedures for monitoring operations proposed here are described in the following two publications: (a) Isolation and Identification of Avian Pathogens, American Association of Avian Pathologists, Texas A & M University, College Station, Texas 77843, 1975 and (b) Culture Methods for the Detection of Animal Salmonellosis and Arizonosis, Iowa State University Press, Ames, Iowa 50010, 1976.

will be designed to include detection of Salmonella species.

[41 FR 48726, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 147.15 Laboratory procedure recommended for the bacteriological examination of mycoplasma reactors.[4]

(a) Turbinates, trachea, air sacs, sinuses, nasal passages, respiratory exudates, synovial fluid, eggs (including yolk, yolk sacs, membranes and allantoic fluid), should be directly sampled with sterile swabs. Aseptic techniques are very important as some organisms may not be suppressed by the antimicrobial agents used in this procedure. Tissue suspensions from large volumes are sometimes desirable from the sites listed above and occasionally from the oviduct and cloaca. Tissues should be ground or blended completely in 10 times their volume of Mycoplasma Broth Medium (MBM). (See paragraph (e) of this section.) Specimens submitted to referral laboratories in order of preference for recovery of the mycoplasma organisms are: (1) live birds, (2) refrigerated fresh tissues, (3) tissue specimens packed with dry ice.

(b) Inoculate 5–10 ml of MBM with a swab, wire loop or 0.1 ml of the tissue suspension. When evidence of growth is observed (lowered pH or turbidity of broth) transfer each broth culture as needed to maintain the original isolates. Incubate tubes at 37°C for at least 21 days before discarding as negative. When growth is first observed or if no growth occurs by the *4th or 5th* day of incubation, inoculate broth culture onto a plate of Mycoplasma Agar Medium (MAM). (See paragraph (f) of this section.) Several cultures may be inoculated on one plate by using a wire loop or a cotton swab. Incubate plates 3–5 days at 37°C in a high humidity chamber. If preferred, 5 percent CO_2 may be added or a candle jar may be used. Tiny circular and translucent colonies with elevated centers are very suggestive of mycoplasma. Indirect lighting and a low power or dissecting microscope are recommended for observation of the colonies as they are rarely more than 0.2–0.3 mm in diameter.

(c) Isolates must be serotyped.

(1) Isolates may be shipped in MBM with ice packs if shipment will be in transit less than 2–3 days. Longer shipments require freezing of the MBM with dry ice, or shipping MAM slants at room temperature. Isolates must have indications of growth before shipment is made.

(2) Isolates may be stored in MBM at −20°C for 2–3 weeks, or they may be stored at −68°C for several years.

(d) Alternate method of culture: An overlay enrichment culture for fastidious and sensitive mycoplasma, especially for *M. meleagridis* should be included.

(1) Pour 2–3 ml of MAM into a test tube and tilt the tube until a slant (approximately 45°) is obtained. Other containers are acceptable.

(2) Overlay the slant with sufficient MBM, so that the media (including inoculum) covers the agar slope.

(3) Inoculate the culture as indicated in paragraph (b) of this section.

(4) Incubate and examine the overlay as indicated in paragraph (b) of this section.

(e) Preparation of media components:[5]

(1) Deionized distilled water suitable for cell culture fluids should be used.

(2) All glassware should be carefully washed with a nonresidue detergent such as Alcojet and rinsed three times in tap water and twice in deionized distilled water.[6]

(3) Thallium acetate in a 10 percent solution is added to an approximate final concentration of 1:4000; however, highly contaiminated specimens may require a final concentration of

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[4] Yoder, H. W., Jr., "Mycoplasmosis." In: Isolation and Identification of Avian Pathogens. (Stephen B. Hitchner, Chairman, Charles H. Domermuth, H. Graham Purchase, James E. Williams.) 1980, pp. 40–42, Creative Printing Company, Inc., Endwell, NY 13760.

[5] Trade names are used in these procedures solely for the purpose of providing specific information. Mention of a trade name does not constitute a guarantee or warranty of the product by the U.S. Department of Agriculture or an endorsement over other products not mentioned.

[6] Alcojet is available from: Alconox, Inc., New York, NY 10003.

1:2000.[7] Thallium acetate is added to deionized distilled water first, except as noted in paragraph (e)(4) of this section, to prevent the precipitation of proteins.

(4) Mycoplasma Broth Base, dextrose, phenol red, and cysteine hydrochloride are added to deionized distilled water first if autoclave sterilization is used.[8] Thallium acetate and then the remaining components are added aseptically after cooling the autoclaved media to 45°C or less.

(5) Use sterile deionized distilled water to reconstitute penicillin.

(6) Sterile serum should be inactivated by heating at 56°C for 30 minutes. Swine serum may be used for *M. gallisepticum*, *M. synoviae*, *M. gallinarum*, and *M. meleagridis* isolation; however, horse serum is usually recommended for *M. meleagridis* isolation.

(7) Phenol red should be prepared as a 1 percent solution.

(8) NAD (beta nicotinamide adenine dinucleotide or coenzyme I) should be prepared as a 1 percent solution.[9]

(9) Cysteine hydrochloride, prepared as a 1 percent solution, is used to reduce the NAD for *M. synoviae* growth.

(10) A purified agar product such as Nobel (Special agar) is used in the MAM.[10]

(11) Adjust the pH with NaOH.

(12) Sterilization may be accomplished by two methods:

(i) Filtration sterilization through a 0.20 micron filter is the recommended method. Aseptic techniques must be utilized.

(ii) Autoclave sterilization at 120°C, 15 pounds pressure (103 kPa), for 15 minutes may be used, if preferred, when following the procedure described in paragraph (e)(4) of this section.

(13) Phenol red, dextrose, and NAD may be omitted when culturing for *M. meleagridis* and *M. gallinarum*.

(14) When culturing for *M. meleagridis* from contaminated samples include 100 units/ml of Polymyxin B in MBM.

(f) Mycoplasma Broth Medium (Frey) is prepared as follows: To 850-880 ml of deionized distilled water;

Add:
Thallium acetate (ml)—2.5 (1:4000)
Potentially contaminated samples (ml)—5.0 (1:2000)
Mycoplasma Broth Base (g)—22.5
Aqueous penicillin (units)—500,000
Sterile serum (ml)—120 to 150.0
Phenol red plus (ml)—2.5
NAD (ml)—12.5
Cysteine hydrochloride (ml)—12.5
Dextrose (g)—1.0-1.5
Adjust pH to 7.8
Filter sterilize

(1) Broth may be stored at 4°C for at least 2 weeks or at −40°C for longer periods.

(g) Mycoplasma Agar Medium (Frey) is prepared as follows: To 850-880 ml of deionized distilled water;

Add:
Mycoplasma Broth Base (g)—22.5
Adjust pH to 7.8
Purified agar (g)—18.0
Autoclave and cool in 45°C water bath
Thallium acetate (ml)—2.0; (1:4000)
Sterile serum at 45°C (ml)—150.0
Aqueous penicillin (units)—400,000
NAD (ml)—12.5
Cysteine hydrochloride (ml)—12.5

(1) Rotate flask gently and pour about 15 ml of media into each petri dish.

(2) Stack petri dishes only 2-3 high in a 37°C incubator up to 2 hours to remove excess moisture.

(3) Wrap inverted plates in sealed bundles and store at 4°C for not more than 15 days.

(h) New component or media batches should be monitored to compensate for changes in formulation due to alterations of purity, concentration, preparation, etc. A known series of titrations from a single culture should be made on both new and old media. The media should be compared on the basis of growth, colony size, and numbers of colonies which develop.[11]

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[7] Thallium acetate may be obtained from Fischer Scientific Company.

[8] Mycoplasma Broth Base may be obtained from: (a) Product #M 33600, Gibco Diagnostics, 2801 Industrial Drive, Madison, WI 53711. (b) Product #3900-3212, Scott Laboratories, Inc., 8 Westchester Plaza, Elmsford, NY 10523.

[9] NAD Grade III may be obtained from: Sigma Chemical Company, P.O. Box 14508, St. Louis, MO 63178.

[10] Noble Agar may be obtained from: Difco Laboratories, Box 1058-A, Detroit, MI 48201.

[47 FR 21995, May 20, 1982]

§ 147.16 Procedure for the evaluation of mycoplasma reactors by in vivo bioassay (enrichment).

This procedure has been shown to be sensitive enough to detect less than 100 mycoplasma organisms under proper conditions.[12] Proper conditions are defined in this section.

(a) Obtain chickens or turkeys (test birds) which are at least 3 weeks of age and are free of *M. gallisepticum, M. synoviae,* and *M. meleagridis* and transport them in a manner to prevent their being contaminated by any infectious avian disease.

(1) Maintain test birds in an area that has been effectively cleaned and disinfected.

(2) The area should be isolated from other birds or animals.

(3) Personnel caring for the test birds should take the necessary precautions (see § 147.26(b)) to prevent the mechanical transfer of infectious avian diseases from other sources.

(b) Test birds to be used for inoculation with contaminated tissues should be serologically negative by the serum plate agglutination test.

(1) Inoculated test birds should be isolated from non-inoculated control birds for the length of any experiment.

(c) Aseptically obtain tracheal, turbinate, and sinus mucosa, lung and sinus exudates, cervical, thoracic, and abdominal airsac tissues (including lesions), and portions of oviduct and synovial fluid from at least four suspect, donor birds. In a sterile device, blend the tissues completely in four times their volume of Mycoplasma Broth Medium (Frey), (see § 147.15(e)). Suspensions may be made from tissue pools. Inoculate test birds within 30 minutes for preparation of suspensions.

(1) Inoculate at least four test birds for each suspension pool via the abdominal air sac and infraorbital sinus, with up to ½ ml of inoculum per site.

(2) Test birds should be bled every 7 days for 35 days to identify sero-converters.

(3) At 35 days, test birds should be sacrificed and bacteriologic isolation and identification of mycoplasma attempted (see § 147.15). Note especially the sites of inoculation for typical gross or microscopic mycoplasma lesions.

(d) Donor birds are considered infected when:

(1) Test birds have serum plate antibodies for the mycoplasma for which the donor birds were tested, regardless of HI test results, *and* control birds stay serologically negative; or

(2) Mycoplasma organisms are isolated from the test birds and serotyped positive for the mycoplasma for which the donor birds were tested, *and* control birds stay serologically and culturally negative.

(e) Laboratory findings may be verified by direct cultures of material from sick birds or by inoculating seronegative birds from the suspect flock and comparing serological findings with those from the test birds.

[47 FR 21996, May 20, 1982]

Subpart C—Sanitation Procedures

§ 147.21 Flock sanitation.

To aid in the maintenance of healthy flocks, the following procedures should be practiced:

(a) Baby poultry should be started in a clean brooder house and maintained in constant isolation from older birds and other animals. Personnel that are in contact with older birds and other animals should take precautions, including disinfection of footwear and change of outer clothing, to prevent the introduction of infection through droppings that may adhere to the shoes, clothing, or hands. (See § 147.24(a).)

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[11] "Laboratory Procedures and Medium For The Isolation Of Mycoplasma From Clinical Materials." *Laboratory Diagnosis of Mycoplasma in Food Animals,* Proceedings of Nineteenth Annual Meeting, The American Association of Veterinary Laboratory Diagnosticians, 1976, pp. 106-115, AAVLD, 6101 Mineral Point Road, Madison, WI 53705.

[12] Research results are described in the following two publications: (a) Bigland, C. H. and A. J. DaMassa, "A Bio-Assay for Mycoplasma Gallisepticum." In: United States Livestock Sanitary Association Proceedings, 67th, 1963, pp. 541-549. (b) McMartin, D. A., "Mycoplasma Gallisepticum in the Respiratory Tract of the Fowl." In: The Veterinary Record, September 23, 1967, pp. 317-320.

(b) Range used for growing young stock should not have been used for poultry the preceding year. Where broods of different ages must be kept on the same farm, there should be complete depopulation of brooder houses and other premises following infection of such premises by any contagious disease.

(c) Poultry houses should be screened and proofed against free-flying birds. An active rodent eradication campaign is an essential part of the general sanitation program. The area adjacent to the poultry house should be kept free from accumulated manure, rubbish, and unnecessary equipment. Dogs, cats, sheep, cattle, horses, and swine should never have access to poultry operations. Visitors should not be admitted to poultry areas, and authorized personnel should take the necessary precautions to prevent the introduction of disease.

(d) Poultry houses and equipment should be thoroughly cleaned and disinfected prior to use for a new lot of birds. (See § 147.24(a).) Feed and water containers should be situated where they cannot be contaminated by droppings and should be frequently cleaned and disinfected. Dropping boards or pits should be constructed so birds do not have access to the droppings.

(e) Replacement breeders shall be housed at the proper density consistent with the type of building and locality and which will allow the litter to be maintained in a dry condition. Frequent stirring of the litter may be necessary to reduce excess moisture and prevent surface accumulation of droppings. Slat or wire floors should be constructed so as to permit free passage of droppings and to prevent the birds from coming in contact with the droppings. Nesting areas should be kept clean and, where appropriate, filled with clean nesting material.

(f) When an outbreak of disease occurs in a flock, dead or sick birds should be taken, by private carrier, to a diagnostic laboratory for complete examination. All Salmonella cultures isolated should be typed serologically, and complete records maintained by the laboratory as to types recovered from each flock within an area. Records on isolations and serological types should be made available to Official State Agencies or other animal disease control regulatory agencies in the respective States for followup of foci of infection. Such information is necessary for the development of an effective Salmonella control program.

(g) Introduction of started or mature birds should be avoided to reduce the possible hazard of introducing infectious diseases. If birds are to be introduced, the health status of both the flock and introduced birds should be evaluated.

(h) In rearing broiler or replacement stock, a sound and adequate immunization program should be adopted. Since different geographic areas may require certain specific recommendations, the program recommended by the State experiment station or other State agencies should be followed.

(i) Feed, pelleted by heat process, should be fed to all age groups. Proper feed pelleting procedures can destroy many disease producing organisms contaminating feedstuffs.

[36 FR 23121, Dec. 3, 1971, as amended at 41 FR 14257, Apr. 2, 1976; 41 FR 48726, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 50 FR 19900, May 13, 1985]

§ 147.22 Hatching egg sanitation.

Hatching eggs should be collected from the nests at frequent intervals and, to aid in the prevention of contamination with disease causing organisms, the following practices should be observed:

(a) Cleaned and disinfected containers should be used in collecting the eggs, and precautions taken to prevent contamination from organisms that may be present on the hands or clothing of the person making the collection.

(b) Dirty eggs should not be used for hatching purposes and should be collected in a separate container from hatching eggs. Slightly soiled eggs may be dry cleaned by hand or motor driven buffer.

(c) The visibly clean eggs should be fumigated as described in § 147.25(a) as soon as possible after collection or otherwise sanitized. The sanitized eggs shall be stored in a cool place at temperatures which will prevent the eggs from sweating at any time.

(d) Egg handlers should thoroughly wash their hands with soap and water and change to clean outer garments prior to handling the sanitized eggs. Sanitized eggs should be immediately removed from the cleaning and grading area and preferably removed to a separate clean and sanitized room. A wall-installed fumigation cabinet (or authorized sanitizing equipment) through which eggs can be passed from the receiving and cleaning area to the sanitary packing and storage areas is a good practice.

(e) The sanitized eggs should be placed in new flats or sanitized reusable flats or racks. New or clean, fumigated, or otherwise sanitized used cases should be utilized for packing. Proper temperature and humidity in the egg cleaning, packing, and storage areas should be maintained. Eggs should be stored no longer than necessary before setting.

(f) The entire egg processing area should be cleaned and sanitized daily on a routine basis; dust, insects, feathers, and other airborne debris should be effectively controlled to prevent recontamination of sanitized eggs. Ink stamps and pads shall be maintained in a sterile condition.

(g) The egg processing building or area should be designed, located, and constructed of such materials as to assure that proper egg sanitation procedures can be carried out, and that the building itself can be easily, effectively, and routinely sanitized. The egg processing building or area should be considered part of a hatchery and the same construction details and physical and personnel sanitation requirements implemented.

[36 FR 23121, Dec. 3, 1971, as amended at 41 FR 14257, Apr. 2, 1976; 41 FR 48726, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19806, May 10, 1984]

§ 147.23 Hatchery sanitation.

An effective program for the prevention and control of Salmonella and other infections should include the following measures:

(a) The hatchery building should be arranged so that separate rooms, with separate ventilation, are provided for each of the four operations: Egg receiving, incubation and hatching, holding of baby poultry, and disposal of offal and cleaning of trays. These rooms should be placed under isolation so that admission is granted only to specifically authorized personnel who have taken proper precautions to prevent introduction of disease.

(b) The hatchery rooms, and tables, racks, and other equipment in them should be thoroughly cleaned and disinfected frequently. All hatchery wastes and offal should be burned or otherwise properly disposed of, and the containers used to remove such materials should be cleaned and sterilized after each use.

(c) The hatching compartments of incubators, including the hatching trays, should be thoroughly cleaned and fumigated or otherwise sanitized after each hatch.

(d) Only clean eggs should be used for hatching purposes. All eggs set should be fumigated or otherwise sanitized prior to setting or as soon as possible (preferably within 12 hours) after they are placed in the incubator. They should also be fumigated or otherwise sanitized after transfer to a separate hatcher. (See § 147.25(d).)

(e) Only new or clean, fumigated, or otherwise sanitized egg cases should be used for transportation of hatching eggs. Soiled egg case fillers should be destroyed.

(f) Day-old chicks, poults, or other newly hatched poultry should be distributed in clean, new boxes. All crates and vehicles used for transporting started or adult birds should be cleaned and disinfected after each use.

[36 FR 23121, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19806, May 10, 1984]

§ 147.24 Cleaning and disinfecting.

The following procedures are recommended:

(a) In the poultry houses, hatchery rooms and delivery trucks:

(1) Settle dust by spraying lightly with the disinfectant to be used.

(2) Remove all litter and droppings to an isolated area where there is no opportunity for dissemination of any infectious disease organisms that may be present. Housing where poultry infected with a mycoplasmal disease were kept should remain closed for 7 days before removal of the litter.

(3) Scrub the walls, floors, and equipment with a hot soapy water solution. Rinse to remove soap.

(4) Spray with a disinfectant which is registered by the Environmental Protection Agency as germicidal, fungicidal, pseudomonocidal, and tuberculocidal, in accordance with the specifications for use, as shown on the label of such disinfectant.

(b) In the hatchers:

(1) Remove trays and all controls and fans for separate cleaning. The ceiling, walls, and floors should be thoroughly wetted with a stream of water; then scrubbed with a hard bristle brush. Rinse until there is no longer any deposit on the walls, particularly near the fan opening.

(2) Replace the cleaned fans and controls. Replace the trays, preferably still wet from cleaning, and bring the incubator to normal operating temperature.

(3) The hatcher should be fumigated as described in § 147.25(e) or otherwise sanitized prior to the transfer of the eggs.

(c) If the same machine is used for incubating and hatching, the entire machine should be cleaned after each hatch. A vacuum cleaner should be used to remove dust and down from the egg trays; then the entire machine should be vacuumed, mopped, and fumigated according to the procedures described in § 147.25(b) (3), (4), and (5) or otherwise sanitized.

[36 FR 23121, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19806, May 10, 1984]

§ 147.25 Fumigation.

Fumigation may be used for sanitizing eggs and hatchery equipment as an essential part of a sanitation program.

(a) Fumigation of clean eggs after collection should be done as follows:

(1) Provide a room or cabinet proportionate to the number of eggs to be handled. The room or cabinet should be airtight and must be equipped with a fan to circulate the gas during fumigation and to expel it after fumigation.

(2) The eggs should be placed on wire racks, in wire baskets, or on cup-type egg flats stacked outside of the egg cases (to permit air circulation) and exposed to circulating formaldehyde gas.

(3) Formaldehyde gas is provided by mixing 0.6 gram of potassium permanganate with 1.2 cc. of formalin (37.5 percent) for each cubic foot of space in the room. The ingredients should be mixed in an earthenware or enamelware container having a capacity at least 10 times the volume of the total ingredients.

(4) Circulate the gas within the room for 20 minutes; then expel.

(5) The temperature in the cabinet during fumigation should be at least 70° F., and the relative humidity above 70 percent.

(b) Eggs should be fumigated at the hatchery prior to setting or as soon as possible after setting (preferably within 12 hours). Single or repeated fumigation of eggs in the setter may be practiced, but the fumigation schedule should be such that no eggs are fumigated during the period from the 24th to the 84th hour of incubation. The following procedure should be used:

(1) Determine the size of the incubator by multiplying the length times the width times the height.

(2) After setting the eggs and allowing temperature and humidity to regain normal operating levels, release formaldehyde gas into the incubator.

(3) For each cubic foot of space in the incubator, use 0.4 grams of potassium permanganate and 0.8 cc. of formalin (37.5 percent). For mixing the fumigant, use an earthenware or enamelware container having the capacity of at least 10 times the volume of the total ingredients.

(4) Close vents and doors but keep circulating fan operating, and continue fumigation for 20 minutes with

normal operating temperature and humidity.

(5) After 20 minutes of fumigation, the vents should be opened to the normal operating positions to release the gas.

(c) Eggs which have not been fumigated in the hatchery as described in paragraph (b) of this section should be fumigated after the 84th hour of incubation. The procedure described in paragraph (b) of this section should be followed.

(d) All eggs should be fumigated after transfer to a separate hatcher, preferably as soon as the temperature and humidity regain normal operating levels. The procedure described in paragraph (b) of this section should be followed.

(e) Empty hatchers should be fumigated between each hatch. After the interior of the hatcher has been thoroughly cleaned and the cleaned trays returned, the following procedure should be followed:

(1) After temperature and humidity are brought to normal operating levels, use 0.6 grams of potassium permanganate and 1.2 cc. of formalin (37.5 percent) per cubic foot of space in the hatcher.

(2) Close the doors and vents and leave closed at least 3 hours, preferably overnight.

(f) The cheesecloth method of fumigation described in this paragraph may be used in lieu of the chemical method described in paragraph (b) of this section, using 0.6 cc. of formalin (37.5 percent) per cubic foot of space in the incubator, or in lieu of the chemical method described in paragraph (e) of this section, using 0.9 cc. of formalin (37.5 percent) for each cubic foot of space in the empty hatcher.

(1) Enough cheesecloth should be used to absorb all of the formalin that is to be used for the fumigation.

(2) The formalin-saturated cheesecloth should be hung in the cabinet in such a manner as to permit the circulating air to evaporate all the formalin. This will require longer than 20 minutes.

(3) Care should be taken to prevent the cheesecloth from blocking the air movement created by the fans.

(4) The cheesecloth method is not suitable for still air machines.

[36 FR 23121, Dec. 3, 1971, as amended at 41 FR 14257, Apr. 2, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19807, May 10, 1984]

§ 147.26 Procedures for establishing isolation and maintaining sanitation and good management practices for the control of Salmonella and Mycoplasma infections.

(a) The following procedures are required for participation under the U.S. Sanitation Monitored, U.S. M. Gallisepticum Clean, and U.S. M. Synoviae Clean classifications:

(1) Allow no visitors except under controlled conditions which insure sanitation. Such conditions shall be approved by the Official State Agency and the Service;

(2) Maintain breeder flocks on farms free from market birds, or follow proper isolation procedures as approved by the Official State Agency;

(3) Eliminate other domesticated fowl from breeder farm;

(4) Dispose of all dead birds by burning, deep burial, or by putting them into special disposal pits.

(b) Recommended procedures:

(1) Avoid the introduction of Salmonella, Mycoplasma gallisepticum, or Mycoplasma synoviae infected poultry;

(2) Prevent indirect transmission from outside sources through contaminated equipment, footwear, clothing, vehicles, or other mechanical means;

(3) Provide adequate isolation of breeder flocks to avoid airborne transmission from infected flocks;

(4) Minimize contact of breeder flocks with free-flying birds;

(5) Keep the rodent population and other pests under control;

(6) Tailor vaccination programs to needs of farm and area;

(7) Clean and disinfect equipment after each use;

(8) Provide clean footwear and provide an adequate security program;

(9) Clean and disinfect houses before introducing a new flock;

(10) Use well-drained range;

(11) Use clean, dry litter free of mold;

(12) Keep accurate records of death losses;

(13) Seek services of veterinary diagnostician if unaccountable mortality or signs of disease occur;

(14) Adopt and maintain a clean-egg program.

(15) Use only crates and vehicles that have been cleaned and disinfected in accordance with the provisions of § 147.24(a) to haul live poultry to and from the premises.

(Approved by the Office of Management and Budget under control number 0579-0007)

[36 FR 23121, Dec. 3, 1971, as amended at 40 FR 1504, Jan. 8, 1975; 41 FR 48727, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979; 47 FR 746, Jan. 7, 1982; 47 FR 21996, May 20, 1982; 48 FR 57473, Dec. 30, 1983]

§ 147.27 Procedures recommended to prevent the spread of disease by artificial insemination of turkeys.

(a) The vehicle transporting the insemination crew should be left as far as practical from the turkey pens.

(b) The personnel of the insemination crew should observe personal cleanliness, including the following sanitary procedures:

(1) Outer clothing should be changed between visits to different premises so that clean clothing is worn upon entering each premises. The used apparel should be kept separate until laundered. This also applies to gloves worn while handling turkeys;

(2) Boots or footwear should be cleaned and disinfected between visits to different premises;

(3) Disposable caps should be provided and discarded after use on each premises.

(c) The use of individual straw or similar technique is highly recommended. Insemination equipment which is to be reused should be cleaned and disinfected before reusing. Equipment used for the convenience of the workers should not be moved from premises to premises.

(d) No obviously diseased flock should be inseminated. If evidence of active disease is noted after insemination is begun, operations should be stopped and the hatchery notified.

(e) Care should be taken during the collection of semen to prevent fecal contamination. If fecal material is present, it should be removed before the semen is collected. Likewise, care should be taken not to introduce fecal material into the oviduct of the hen.

Subpart D—[Reserved]

Subpart E—Procedure for Changing National Poultry Improvement Plan

§ 147.41 Definitions.

Except where the context otherwise requires, for the purposes of this subpart the following terms shall be construed, respectively, to mean:

(a) *Plan or NPIP.* The National Poultry Improvement Plan.

(b) *Plan Conference.* A meeting convened for the purpose of recommending changes in the provisions of the Plan.

(c) *Department.* The U.S. Department of Agriculture.

(d) *Service.* The Animal and Plant Health Inspection Service, Veterinary Services, of the Department.

(e) *State.* Any State, the District of Columbia, or Puerto Rico.

(f) *Egg type chickens.* Chickens bred for the primary purpose of producing eggs for human consumption.

(g) *Meat type chickens.* Chickens bred for the primary purpose of producing meat.

(h) *Waterfowl.* Domesticated fowl that normally swim, such as ducks and geese.

(i) *Exhibition Poultry.* Domesticated fowl which are bred for the combined purposes of meat or egg production and competitive showing.

(j) *Game birds.* Domesticated fowl, such as pheasants, partridge, quail, grouse, and guineas, but not doves and pigeons.

[36 FR 23121, Dec. 3, 1971, as amended at 38 FR 3038, Feb. 1, 1973. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 147.42 General.

Changes in this subchapter shall be made in accordance with the procedure described in this subpart: *Provided,* That the Department reserves the right to make changes in this subchapter without observance of such procedure when such action is deemed necessary in the public interest.

§ 147.43 General Conference Committee.

(a) The General Conference Committee shall consist of the Assistant Secretary of Agriculture for Marketing and Transportation Services, or his/her designee, one member-at-large who is a participant in the National Poultry Improvement Plan and who shall be designated as vice chairperson, and one member to be elected, as provided in paragraph (b) of this section, from each of the following regions:

(1) North Atlantic: Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, and Pennsylvania.

(2) East North Central: Ohio, Indiana, Illinois, Michigan, and Wisconsin.

(3) West North Central: Minnesota, Iowa, Missouri, North Dakota, South Dakota, Nebraska, and Kansas.

(4) South Atlantic: Delaware, District of Columbia, Maryland, Virginia, West Virginia, North Carolina, South Carolina, Georgia, Florida, and Puerto Rico.

(5) South Central: Kentucky, Tennessee, Alabama, Mississippi, Arkansas, Louisiana, Oklahoma, and Texas.

(6) Western: Montana, Idaho, Wyoming, Colorado, New Mexico, Arizona, Utah, Nevada, Washington, Oregon, California, Alaska, and Hawaii.

(b) The regional committee members and their alternates will be elected by the official delegates of the respective regions and the member-at-large will be elected by all official delegates. There shall be at least two nominees for each position, and the voting shall be by secret ballot.

(c) Three regional members shall be elected at each Plan Conference. All members shall serve for a period of 4 years, subject to the continuation of the Committee by the Secretary of Agriculture, and may not succeed themselves: *Provided,* That an alternate member who assumed a Committee member vacancy following mid-term would be eligible for re-election to a full term. When there is a vacancy for the member-at-large position, the General Conference Committee shall make an interim appointment and the appointee shall serve until the next Plan Conference at which time an election will be held. If a vacancy occurs due to both a regional member and alternate being unable to serve, the vacant position will be filled by an election at the earliest regularly scheduled national or regional Plan Conference, where members of the affected region have assembled.

(d) The duties and functions of the General Conference Committee shall be as follows:

(1) Assist the Department in planning, organizing, and conducting the biennial National Poultry Improvement Plan Conference.

(2) Recommended whether new proposals (i.e., proposals that have not been submitted as provided in § 147.44) should be considered by the delegates to the Plan Conference.

(3) During the interim between Plan Conferences, represent the cooperating States in:

(i) Advising the Department with respect to administrative procedures and interpretations of the Plan provisions as contained in 9 CFR.

(ii) Assisting the Department in evaluating comments received from interested persons concerning proposed amendments to the Plan provisions.

(iii) Recommending to the Secretary of Agriculture any changes in the provisions of the Plan as may be necessitated by unforeseen conditions when postponement until the next Plan Conference would seriously impair the operation of the program. Such recommendations shall remain in effect only until confirmed or rejected by the next Plan Conference, or unitl rescinded by the committee.

(4) Serve as a forum for the study of problems relating to poultry health and as the need arises, to make specific recommendations to the Secretary of Agriculture concerning ways in which the Department may assist the industry in solving these problems.

[36 FR 23121, Dec. 3, 1971, as amended at 40 FR 1505, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 45 FR 10316, Feb. 15, 1980; 47 FR 21996, May 20, 1982; 50 FR 19900, May 13, 1985]

§ 147.44 Submitting, compiling, and distributing proposed changes.

(a) Changes in this subchapter may be proposed by any participant, Official State Agency, the Department, or other interested person or industry organization.

(b) Except as provided in § 147.43(d)(2), proposed changes shall be submitted in writing so as to reach the Service not later than 150 days prior to the opening date of the Plan Conference, and participants in the Plan shall submit their proposed changes through their Official State Agency.

(c) The name of the proponent shall be indicated on each proposed change when submitted. Each proposal should be accompanied by a brief supporting statement.

(d) The Service will notify all persons on the NPIP mailing lists concerning the dates and general procedure of the conference. Hatchery and dealer participants will be reminded of their privilege to submit proposed changes and to request copies of all the published proposed changes.

(e) The proposed changes, together with the names of the proponents and supporting statements, will be compiled by the Service and issued in processed form. When two or more similar changes are submitted, the Service will endeavor to unify them into one proposal acceptable to each proponent. Copies will be distributed to officials of the Official State Agencies cooperating in the NPIP. Additional copies will be made available for meeting individual requests.

[36 FR 23121, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19807, May 10, 1984]

§ 147.45 Official delegates.

Each cooperating State shall be entitled to one official delegate for each of the programs prescribed in Subparts B, C, D, and E of Part 145 of this chapter in which it has one or more participants at the time of the Conference. The official delegates shall be elected by a representative group of participating industry members and be certified by the Official State Agency. It is recommended but not required that the official delegates be Plan participants. Each official delegate shall endeavor to obtain, prior to the Conference, the recommendations of industry members of his State with respect to each proposed change.

[41 FR 48727, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 45 FR 10317, Feb. 15, 1980]

§ 147.46 Committee consideration of proposed changes.

(a) The following four committees shall be established to give preliminary consideration to the proposed changes falling in their respective fields:

(1) Egg-type chickens.

(2) Meat-type chickens.

(3) Turkeys.

(4) Waterfowl, exhibition poultry, and game birds.

(b) Each official delegate shall be appointed a voting member in one of the committees specified in paragraph (a) of this section.

(c) Since several of the proposals may be interrelated, the committees shall consider them as they may relate to others, and feel free to discuss related proposals with other committees.

(d) The committees shall make recommendations to the conference as a whole concerning each proposal. The committee report shall show any proposed change in wording and the record of the vote on each proposal, and suggest an effective date for each proposal recommended for adoption. The individual committee reports shall be submitted to the chairman of the conference, who will combine them into one report showing, in numerical sequence, the committee recommendations on each proposal.

(e) The committee meetings shall be open to any interested person. Advocates for or against any proposal should feel free to appear before the appropriate committee and present their views.

[36 FR 23121, Dec. 3, 1971, as amended at 41 FR 48727, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 147.47 Conference consideration of proposed changes.

(a) The chairman of the conference shall be a representative of the Department.

(b) At the time designated for voting on proposed changes by the official delegates, the chairman of the General Conference Committee and the four committee chairmen shall sit at the speaker's table and assist the chairman of the conference.

(c) Each committee chairman shall present the proposals which his committee approves or recommends for adoption as follows: "Mr. Chairman. The committee for Egg-type chickens recommends the adoption of Proposal No. ———, for the following reasons (stating the reasons): I move the adoption of Proposal No. ———." A second will then be called for. If the recommendation is seconded, discussion and a formal vote will follow.

(d) Each committee chairman shall present the proposals which his committee does not approve as follows: "Mr. Chairman. The Committee for Egg-type chickens does not approve Proposal No. ———." The chairman will then ask if any official delegate wishes to move for the adoption of the proposal. If moved and seconded, the proposal is subject to discussion and voted. If there is no motion for approval, or if moved but not seconded, there can be no discussion or vote.

(e) Discussion on any motion must be withheld until the motion has been properly seconded, except that the delegate making the motion is privileged, if he desires, to give reasons for his motion at the time of making it. To gain the floor for a motion or for discussion on a motion, the official delegate in the case of a motion, or anyone in case of discussion on a motion, shall rise, address the chair, give his name and State, and be recognized by the chair before proceeding further. While it is proper to accept motions only from official delegates and to limit voting only to such delegates, it is, however, equally proper to accept discussion from anyone interested. To conserve time, discussion should be pointed and limited to the pertinent features of the motion.

(f) Proposals that have not been submitted in accordance with § 147.44 will be considered by the conference only with the unanimous consent of the General Conference Committee. Any such proposals must be referred to the appropriate committee for consideration before being presented for action by the conference.

(g) Voting will be by States, and each official delegate, as determined by § 147.45, will be allowed one vote on each proposal pertaining to the program prescribed by the subpart which he represents.

(h) A roll call of States for a recorded vote will be used when requested by a delegate or at the discretion of the chairman.

(i) All motions on proposed changes shall be for adoption.

(j) Proposed changes shall be adopted by a majority vote of the official delegates present and voting.

(k) The conference shall be open to any interested person.

[36 FR 23121, Dec. 3, 1971, as amended at 41 FR 48727, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 147.48 Approval of conference recommendations by the Department.

Proposals adopted by the official delegates will be recommended to the Department for incorporation into the provisions of the NPIP. The Department reserves the right to approve or disapprove the recommendations of the conference as an integral part of its sponsorship of the National Poultry Improvement Plan.

SUBCHAPTER G—ANIMAL BREEDS

PART 151—RECOGNITION OF BREEDS AND BOOKS OF RECORD OF PUREBRED ANIMALS

DEFINITIONS

Sec.
151.1 Definitions.

CERTIFICATION OF PUREBRED ANIMALS

151.2 Issuance of a certificate of pure breeding.
151.3 Application for certificate of pure breeding.
151.4 Pedigree certificate.
151.5 Alteration of pedigree certificate.
151.6 Statement of owner, agent, or importer as to identity of animals.
151.7 Examination of animal.
151.8 Eligibility of an animal for certification.

RECOGNITION OF BREEDS AND BOOKS OF RECORD

151.9 Recognized breeds and books of record.
151.10 Recognition of additional breeds and books of record.
151.11 Form of books of record.

AUTHORITY: Par. 1606, sec. 201, 46 Stat. 673, as amended; 19 U.S.C. 1202, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes, see 36 FR 24928, Dec. 24, 1971.

DEFINITIONS

§ 151.1 Definitions.

Words used in this part in the singular form shall be deemed to import the plural, and vice versa, as the case may demand. As used in this part, the following words, names, or terms shall have the meanings set forth in this section, unless otherwise clearly indicated by the context.

(a) *The Act.* Item 100.01 in part 1, schedule 1, of title I of the Tariff Act of 1930, as amended (19 U.S.C. 1202, schedule 1, part 1, item 100.01).

(b) *Department.* The United States Department of Agriculture.

(c) *Veterinary Services.* The Veterinary Services unit of the Animal and Plant Health Inspection Services of the Department.

(d) *Deputy Administrator, Veterinary Services.* The Deputy Administrator, Veterinary Services or any officer or employee of Veterinary Services to whom authority has heretofore lawfully been delegated or to whom authority may hereafter lawfully be delegated to act in his stead.

(e) *Inspector.* An inspector of Veterinary Services or of the Bureau of Customs of the United States Treasury Department authorized to perform functions under the regulations in this part.

(f) *Animal.* Any purebred animal imported specially for breeding purposes except a black, silver, or platinum fox, or any fox which is a mutation or type developed therefrom.

(g) *Purebred.* A term applicable to animals which are the progeny of known and registered ancestors of the same recognized breed and for which at least three generations of ancestry can be traced: *Provided, however,* That in the case of sheep registered on the basis of flocks, the term is applicable to animals of a recognized breed which originate in a flock for which available breeding data, as shown in the registry association's records, establish that the flock has been in existence at least ten years.

(h) *Pedigree certificate.* A document issued by a registry association giving the pedigree of an animal and certifying that it is registered in the book of record of the association issuing the document, and containing all pertinent information relating to the registered animal, such as color and natural and artificial markings, a record of the name and address of the breeder, and the name and address of each subsequent owner of the animal.

(i) *Book of record.* A printed book or an approved microfilm record sponsored by a registry association and containing breeding data relative to a large number of registered purebred animals used as a basis for the issuance of pedigree certificates.

(j) *Certificates of pure breeding.* A certificate issued by the Deputy Administrator, Veterinary Services, for Bureau of Customs use only, certifying that the animal to which the certificate refers is a purebred animal of a recognized breed and duly registered in a book of record recognized under the regulations in this part for that breed.

(k) *Agent.* Custom broker or other person authorized to act as agent for the importer or owner of an animal.

(l) *Port of entry.* Any port designated under § 92.3 of this chapter.

(Sec. 201, 46 Stat. 673; 19 U.S.C. 1201, as amended; sec. 101, 76 Stat. 72; 19 U.S.C. 1202)

[23 FR 10103, Dec. 23, 1958, as amended at 24 FR 2643, Apr. 7, 1959; 26 FR 6072, July 7, 1961; 36 FR 23356, Dec. 9, 1971]

CERTIFICATION OF PUREBRED ANIMALS

§ 151.2 Issuance of a certificate of pure breeding.

The Deputy Administrator, Veterinary Services will issue a certificate of pure breeding for an animal claimed to be entitled to free entry under the act provided the requirements of the regulations in this part are complied with. Such certificate will be presented to the owner, agent, or importer who in turn shall present it to the collector of customs at the port where customs entry is made.

[26 FR 6072, July 7, 1961]

§ 151.3 Application for certificate of pure breeding.

An application for a certificate of pure breeding executed by the owner, agent, or importer of an animal shall be made on ANH Form 17-338 (available from the collector of customs) before the animal will be examined as provided in § 151.7. Such application shall be made to the inspector at the port of entry for all animals: *Provided, however,* That the application for a certificate of pure breeding for dogs, other than those regulated under § 92.18 of this chapter, and cats may be made to the inspector either at the port of entry or at any other port where customs entry is made. An agent shall show the inspector written authorization from the owner or importer authorizing him to act for the owner or importer in connection with the application for a certificate of pure breeding.

(Approved by the Office of Management and Budget under control number 0579-0011)

(Sec. 201, 46 Stat. 673; 19 U.S.C. 1201, as amended; sec. 101, 76 Stat. 72; 19 U.S.C. 1201)

[26 FR 6072, July 7, 1961, as amended at 36 FR 23356, Dec. 9, 1971; 48 FR 57473, Dec. 30, 1983]

§ 151.4 Pedigree certificate.

A pedigree certificate for an animal of a breed listed in § 151.9 issued by the custodian of the appropriate book of record listed in said section and on which there has been entered in accordance with the rules of entry of the registry association, a complete record of transfers of ownership from the breeder to and including the United States importer, or a complete record of transfers of ownership from the breeder to and including the person who owns the animal when it is imported into the United States and the name of the United States importer (for example, a lessee), shall be furnished by the owner, agent, or importer to the inspector at the time of the examination of the animal as provided in § 151.7. The inspector will return the document to the party who submitted it. A verbatim translation of the description relating to color and markings shall appear in English in the pedigree certificate for the animal or in a separate certificate appended to the pedigree certificate.

[26 FR 6072, July 7, 1961]

§ 151.5 Alteration of pedigree certificate.

No pedigree certificate which in the opinion of the Deputy Administrator, Veterinary Services has been substantially altered will be accepted.

[23 FR 10104, Dec. 23, 1958]

§ 151.6 Statement of owner, agent, or importer as to identity of animals.

The owner, agent, or importer who applies for a certificate of pure breeding for any animal offered for duty-free entry under this part, shall execute on ANH Form 17-338 a statement that the animal so offered for entry is the animal described in the pedigree certificate furnished to the inspector as prescribed in § 151.4. This form shall be presented to the inspector before the animal and pedigree certificate are examined as provided in § 151.7.

(Sec. 101, 76 Stat. 72; 19 U.S.C. 1202)

[36 FR 23357, Dec. 9, 1971]

§ 151.7 Examination of animal.

(a) For the purpose of determining identity, an examination shall be made by an inspector of each animal for which free entry is claimed under the act. All animals shall be examined at the port of entry: *Provided, however,* That dogs, other than those regulated under § 92.18 of this chapter, and cats may be examined either at the port of entry or at any other port where customs entry is made.

(b) The owner, agent, or importer shall provide adequate assistance and facilities for restraining and otherwise handling the animal and present it in such manner and under such conditions as in the opinion of the inspector will make a proper examination possible. Otherwise, the examination of the animal will be refused or postponed by the inspector until the owner, agent, or importer meets these requirements.

(c) A pedigree certificate, as required by § 151.4 shall be presented at the time of examination to the inspector making the examination in order that proper identification of the animal may be made. When upon such examination of any animal, the color, markings, or other identifying characteristics do not conform with the description given in the pedigree certificate and the owner, agent, or importer desires to pursue the matter further, the inspector shall issue ANH Form 17-419 to the owner, agent, or importer, and shall forward the pedigree certificate for this animal, together with ANH Form 17-419, to the Washington office of Veterinary Services by certified mail. A determination will be made by such office as to the identity of the animal in question and the eligibility of the animal for certification under § 151.2. The pedigree certificate will be returned to the party who submitted it as soon as such determination is made. Removal of an animal from the port where examination is made prior to presentation of the pedigree certificate or other failure to comply with the requirements of this paragraph shall constitute a waiver of any further claim to certification under the regulations in this part.

(Sec. 201, 46 Stat. 673; 19 U.S.C. 1201, as amended; sec. 101, 76 Stat. 72; 19 U.S.C. 1202)

[26 FR 6072, July 7, 1961]

§ 151.8 Eligibility of an animal for certification.

To be eligible for certification under the act, an animal must be purebred of a recognized breed and have been registered in good faith in a book of record listed in § 151.9 and must not have been registered on inspection without regard to purity of breeding.

[23 FR 10104, Dec. 23, 1958]

RECOGNITION OF BREEDS AND BOOKS OF RECORD

§ 151.9 Recognized breeds and books of record.

Breeds of animals and books of record listed in paragraphs (a) and (b) are hereby recognized. Recognition of such breeds and books of record will be continued, however, only if the books of record involved are kept by the custodians thereof in a form which is reasonably current and the book otherwise meets the requirements of this part, in the opinion of the Deputy Administrator, Veterinary Services. When a registry association which publishes a book of record that was recognized in printed form ceases to publish the book in such form and in lieu thereof publishes the book in microfilm form, the recognition of such book of record will be continued only if the book meets the requirements of this part. A copy of each printed volume and microfilm record of a book of record published after the book is recognized under this part shall be sent to Veterinary Services immediately following such publication. All books of record sent to Veterinary Services, Animal and Plant Health Inspection Service, United States Department of Agriculture, shall be submitted through the United States Government Despatch Agency, 26 Federal Plaza, New York, New York 10007, U.S.A.

(a) *Breeds and books of record in countries other than Canada.* Books of the registry associations listed below are recognized for the following breeds: *Provided,* That no Belted Galloway cattle, horse of Criolla, Fjordhest (formerly known as Westland), Holstein, Shetland Pony or Welsh Pony and Cob breed, dog or cat registered in any of the books named shall be certified under the act as purebred unless a pedigree certificate showing three complete generations of known and recorded purebred ancestry of the particular breed involved, issued by the appropriate association listed below, is submitted for such animal.

CATTLE

Code	Name of breed	Book of record	By whom published
1101	Aberdeen-Angus	Aberdeen-Angus Herd Book	Aberdeen-Angus Cattle Society, Hugh R. Neilson, secretary, Pedigree House, 17 Bon-Accord Sq., Aberdeen, Scotland.
1112	......do	New Zealand Aberdeen-Angus Herd Book.	New Zealand Aberdeen-Angus Cattle Breeders' Association, Post Office Box 83, Hastings, New Zealand.
1102	Africander	Africander Cattle Herd Book	The Africander Cattle Breeders' Society, under the supervision and authority of the South African Stud Book Association, E.L. Househam, secretary, 40 Henry St., Bloemfontein, Union of South Africa.
1201	Alderney	Herd Book of the Bailiwick of Guernsey (Alderney Branch).	Royal Alderney Agricultural Society (The Alderney Branch of the Royal Guernsey A. and H. Society), P.D. Sumner, secretary, The Bungalow, Butes, Alderney, Channel Isles.
1202	Ayrshire	Ayrshire Herd Book	Ayrshire Cattle Herd Book Society of Great Britain and Ireland, John Graham, secretary, 1 Racecourse Rd., Ayr, Scotland.
1301	Devon	Davy's Devon Herd Book	Devon Cattle Breeders' Society, Cyril Ernest Berry, secretary, Court House, The Square, Wiveliscombe, Somerset, England.
1302	Dexter	Dexter Herd Book	Dexter Cattle Society, T. S. Pick, secretary, Manor Farm, Stubbs Lane, Lower Kingswood, Tadworth, Surrey, England.
1103	Belted Galloway	Belted Galloway Herd Book	Belted Galloway Cattle Society, J. Campbel Laing, secretary, Galloway Estate Office, Newton Stewart, Wigtownshire, Scotland.
1104	Galloway	Galloway Herd Book	Galloway Cattle Society of Great Britain and Ireland, Donald M. McQueen, secretary, Roughhills, Dalbeattie, Scotland.
1203	Guernsey	English Guernsey Herd Book	English Guernsey Cattle Society, J. W. Barker, secretary, Mappin House, Winsley St., Oxford St., London, W. 1, England.
1204	......do	Herd Book of the Bailwick of Guernsey (Guernsey Branch).	Royal Guernsey Agricultural and Horticultural Society, H. C. Le Page, secretary, States Arcade Balcony, St. Peter Port, Guernsey, Channel Isles.
1105	Hereford	Herd Book of Hereford Cattle	Hereford Herd Book Society, R.J. Bentley, secretary, 3 Offa St., Hereford, England.
1106	Highland	Highland Herd Book	Highland Cattle Society of Scotland, Donald G. Noble, secretary, 17 York Pl., Perth, Scotland.
1205	Holstein-Friesian	Friesch Rundvee-Stamboek	Vereeniging: "Het Friesch Rundvee-Stamboek," Dr. J. M. Dijkstra, secretary, Zuiderplein 2-6, Leeuwarden, The Netherlands.
1206	......do	Nederlandsch Rundvee-Stambook.	Vereeniging: "Het Nederlandsche Rundvee-Stamboek," H. W. J. Dekker, Chief Administrator, Stadhouders-plantsoen 24, 's-Gravenhage, The Netherlands.
1207	Jersey	Jersey Herd Book	Royal Jersey Agricultural and Horticultural Society, H. G. Shepard, secretary, 3 Mulcaster St., St. Helier, Jersey, Channel Isles.
1208	......do	Jersey Herd Book of United Kingdom.	Jersey Cattle Society of the United Kingdom, Edward Ashby, secretary, 19 Bloomsbury Sq., London, W. C. 1, England.
1303	Kerry	British Kerry Cattle Herd Book	British Kerry Cattle Society, R. O. Hubl, secretary, The Milestone, Stanmore Hill, Stanmore, Middlesex, England.
1304	......do	Kerry Cattle Herd Book	Royal Dublin Society, Horace H. Poole, registrar, Ball's Bridge, Dublin, Ireland.
1305	Lincoln Red	Lincoln Red Herd Book	Lincoln Red Cattle Society, W. Dunnaway secretary, Agriculture House, Park St., Lincoln, England.

CATTLE—Continued

Code	Name of breed	Book of record	By whom published
1209	Red Danish	Stambog over Koer af Rod Dansk Malkerace. Stambog over Tyre af Rod Dansk Malkerace. Register-Stambog over Kvaeg af Rod Dansk Malkerace.	De Samvirkende Danske Landboforeninger, A. Wulff Pedersen, secretary, Vindegade 72, Odense, Denmark.
1306	Red Poll	Red Poll Herd Book	Red Poll Cattle Society of Great Britain and Ireland, Inc., A. C. Burton, secretary, 32 Princes St., Ipswich, Suffolk, England.
1307	Shorthorn	Coates's Herd Book	Shorthorn Society of Great Britain and Ireland, Arthur Greenhalgh, secretary, Victoria House, Southampton Row, London, W.C. 1, England.
1107	South Devon	Herd Book of South Devon Cattle.	South Devon Herd Book Society, W. G. Turpitt, secretary, 16 Sherborne Rd., Newton Abbot, Devon, England.
1115	Simmental	Irish Simmental Cattle Society	Irish Simmental Cattle Society Ltd., Springhill Carrigtwohill, Co. Cork, Ireland.
1308	Sussex	Sussex Herd Book	Sussex Herd Book Society, A. G. Holland, secretary, 17 Devonshire St., London, W. 1, England.
1309	Welsh	Welsh Black Cattle Herd Book	Welsh Black Cattle Society, G. Williams Edwards, secretary, 13 Bangor St., Caernarvon, No. Wales.

HORSES

Code	Name of breed	Book of record	By whom published
2201	Arabian	Arab Horse Stud Book	The Arab Horse Society, Col. R. C. de V. Askin, secretary, Beechmead, Rowledge, Farnham, Surrey, England.
2202	do	Polska Ksiega Stadna Koni, Arabskich Czystej Krwi.	Towarzystwo Hodowli Konia Arabskiego, Maria Brykczynska, secretary, Krako 1w, Sarego 2, Poland.
2203	do	General Stud Book	Weatherby & Sons, 15 Cavendish Sq., London, W. 1, England.
2204	do	Registro-Matricula de Caballos de Pura Sangre.	Jefatura de Cria Caballar y Remonta, Don Manuel Diaz Calderon, Secretario Stud-book, Ministerio del Ejercito, Madrid, Spain.
2205	do	Stud Book Argentino	Ministerio de Hacienda de la Nacion, Loteria de Beneficencia Nacional y Casinos, Ricardo A. Maestri, Jefe, Av. Libertador General San Martin 4101, Capital Federal, Republica Argentina.
2206	do	Stud Book Francais Registre des Chevaux de Pur Sang.	Commission du Studbook Francais de Pur Sang, M. Maze-Sencier, Inspecteur General, Chef, Service des Haras, Ministere de l'Agriculture, 78 rue de Varenne (7), Paris, France.
2207	do	Stud Book de Venezuela	Instituto Nacional de Hipodromos, Jorge Coll Nunez, Jefe, Hipodromo "La Rinconada," Caracas, Venezuela.
2208	do	The Arabian Stud Book. (Recognition of this book will be restricted to Arabian horses which originate for importation in Saudi Arabia, or trace to pure Arabian stock of that country.).	The Arabian Horse Club Registry of America, Inc., Henry B. Babson, secretary, 120 So. La Salle St., Chicago 3, Ill.
2304	Arabian	Russian Arabian Stud Book of Moscow, Union of Soviet Socialist Republics.	Ministry of Agriculture USSR, All-Union Research Institute of Horsebreeding.
2101	Belgian	Stud-Book des Chevaux de Trait Belges.	Societe 1 Royale "Le Cheval de Trait Belge," Edgard Bedoret, Secretaire general, 45a rue de l'Ecuyer, Brussels, Belgium.
2209	Cleveland Bay	Cleveland Bay Stud Book	Cleveland Bay Horse Society, Oswald Welford, secretary, The Angelus, Roxby, Staithes, Saltburn, Yorkshire, England.
2102	Clydesdale	Clydesdale Stud-Book	Clydesdale Horse Society of Great Britain & Ireland, Robert Jarvis, secretary, 19 Hillington Gardens, Glasgow, S.W. 2, Scotland.

HORSES—Continued

Code	Name of breed	Book of record	By whom published
2210	Criolla	"Registre Definitivo Seccion" de Registro Genealogico para la Raza Criolla.	Sociedad Rural Argentina, E. F. Garay, Gerente Tecnico, Florida 460, Buenos Aires, Argentina.
2301	Fjordhest (formerly known as Westland).	Stambok over Fjordhest	Statens Stambokkontor, Arne Hogstad, Statens Stambokforer, Munkedamsveien 35 VI, Oslo, Norway.
2211	Hackney	Hackney Stud Book	Hackney Horse Society, R. A. Brown, secretary, 16 Bedford Sq., London, W.C. 1, England.
2212	Holstein	Holsteinisches Gestutbuch	Verband der Zuchter des Holsteiner Pferdes e. V., Herr H. Horstmann, Geschaftsfuhrer, Klostersande 93, Elmshorn, Germany.
2103	Percheron	British Percheron Stud Book	British Percheron Horse Society, A. E. Vyse, secretary, Owen Webb House, Gresham Rd., Cambridge, England.
2104	......do	Stud-Book Percheron de France	Societe 1 Hippique Percheronne de France, E. Lemarie, secretaire general, 7 rue Villette-Gate 1. Nogent-le-Rotrou (E-&-L), France.
2302	Shetland Pony	Shetland Pony Stud-Book	Shetland Pony Stud-Book Society, Thomas H. F. Myles, secretary, 61 George St., Perth, Scotland.
2105	Shire	Shire Horse Stud Book	Shire Horse Society, A. G. Holland, secretary, 17 Devonshire St., London, W. 1, England.
2106	Suffolk	Suffolk Stud-Book	Suffolk Horse Society, Raymond Keer, secretary, 6 Church St., Woodbridge, Suffolk, England.
2213	Thoroughbred	Australian Stud Book	Australian Jockey Club and Victoria Racing Club, W. J. McFadden, Keeper of the Stud Book, 6 Bligh St., Sydney, N.S.W., Australia.
2214	......do	General Stud Book	Weatherby & Sons, 15 Cavendish Sq., London, W. 1, England.
2215	......do	Jamaica Stud-Book	The Jockey Club of Jamaica, Miss L. Pike, secretary, 10 Duke St., Kingston, Jamaica, B.W.I.
2216	......do	Stud Book de Chile	Club Hipico de Santiago, Alejandro Obolensky Dadian, Jefe de Stud-Book, Casilla 3674, Santiago, Chile.
2217	......do	Stud Book de Venezuela	Instituto Nacional de Hipodromos, Jorge Coll Nunez, Jefe, Hipodromo "La Rinconada," Caracas, Venezuela.
2218	......do	New Zealand Stud Book	New Zealand Racing Conference, A. M. McBeath, secretary, P.O. Box 1430, Wellington, C. 1, New Zealand.
2219	......do	Registro-Matricula de Caballos de Pura Sangre.	Jefatura de Cria Caballar y Remonta, Don Manuel Diaz Calderon, Secretario Stud-book, Ministerio del Ejercito, Madrid, Spain.
2220	Thoroughbred	Stud Book Francais Registre des Chevaux de Pur Sang.	Commission du Studbook Francais de Pur Sang, M. Maze-Sencier, Inspecteur General, Chef, Service des Haras, Ministere de l'Agriculture, 78 rue de Varenne (7), Paris, France.
2221	......do	Libro Genealogico dei Cavalli di Puro Sangue.	Jockey Club Italiano, Gen. Federico Garofoli, segretario, Corso Vittorio Emanuele 87, Rome, Italy.
2222	......do	Registre des Chevaux de Pur Sang.	Jockey-Club de Belgique, Lt. Col. Baron Jacques van Zuylen van Nyevelt, Secretaire general, 1 rue Guimard, Brussels 4, Belgium.
2223	......do	Stud Book Brasileiro	Jockey Club Brasileiro, Ricardo Xavier da Silveira, Diretor do Stud Book, Av., Rio Branco 197, Rio de Janeiro, Brazil.
2224	......do	Stud Book Peruano	Jockey Club del Peru, Alberto Alvarez Calderon, Gerente, Union 1066, Lima, Peru.
2225	......do	Stud Book Argentino	Ministerio de Hacienda de la Nacion, Loteria de Beneficencia Nacional y Casinos, Ricardo A. Maestri, Jefe, Av. Libertador General San Martin 4101, Capital Federal, Republica Argentina.

Horses—Continued

Code	Name of breed	Book of record	By whom published
2226	......do	American Stud Book. (Recognition of this book will be restricted to Thoroughbreds imported as follows: (a) Horses bred or born in the United States, shipped to a foreign country and returned to this country; (b) horses bred or born in Great Britain, Northern Ireland, Eire, or France, whose pedigrees trace wholly, or in part, to horses bred or born in the United States; (c) horses from countries where a book of purebred registration for Thoroughbreds does not exist; or (d) horses previously certified for entry under the act and for which Certificates of Foreign Registration were issued by The Jockey Club of New York, and which were subsequently exported to any country and returned to the United States with such certificates.).	The Jockey Club, Mrs. L. Brennan, Registrar, 300 Park Ave., New York 22, N.Y.
2233	......do	Allgemeines deutsches Gestubuch fur Vollblut.	Direktorium fur Vollblutzucht und Rennen, 6 Cologne Weidenpesch, Rennbahnstrasse 100, Postfach 180, Republic of Germany.
2234	......do	Stud Book Uruguayo	Jefe del Stud Book Uruguayo, Jose C. Frigerio, Head, Uruguayan Jockey Club, Montevideo, Uruguay.
2235	......do	The General Stud Book of South Africa.	The Jockey Club of South Africa, Box 3409, Johannesburg, Union of South Africa.
2303	Welsh Pony and Cob	Welsh Stud Book	Welsh Pony & Cob Society, J. A. George, secretary, Offices of the Royal Welsh Agricultural Society, Queen's Rd., Aberystwyth, Cardiganshire, Wales.

Asses

Code	Name of breed	Book of record	By whom published
3001	Poitou	Jack and Jennet Section of Stud-Book ou Livre Genealogique des Animaux Mulassiers due Poitou.	Societe Centrale d'Agriculture des Deux-Sevres R. Martinet, Secretaire, Cite Administrative, rue Duguesclin, Niort (Deux-Sevres), France.

Sheep

Code	Name of breed	Book of record	By whom published
4101	Border Leicester	Border Leicester Flock Book	Society of Border Leicester Sheep Breeders, Robert Jarvis, secretary, Room 273, 93 Hope St., Glasgow, C. 2, Scotland.
4102	Cheviot	Cheviot Sheep Flock Book	Cheviot Sheep Society, Guy H. Armstrong, secretary, Commercial Bank Bldgs., Hawick, Scotland.
4103	Corriedale	Flock Book for Corriedale Sheep in Australia.	The Australian Corriedale Association, H.T.C. Woodfull, secretary, Royal Showgrounds, Epsom Road, Ascot Vale, W. 2, Victoria, Australia.
4104	Corriedale	Corriedale Flock Book (New Zealand).	The Corriedale Sheep Society, Inc., C. H. Lawrence, secretary, 154 Hereford St., Christchurch, New Zealand.
4201	Dorset Horn	Dorset Horn Flock Book	Dorset Horn Sheep Breeders' Association, E. F. B. Lucas, secretary, Bank Chambers, Dorchester, Dorset, England.
4202	Hampshire Down	Hampshire Down Flock Book	Hampshire Down Sheep Breeders' Association, Miss Doris M. Stanbury, secretary, 38 Endless St., Salisbury, Wilts., England.

SHEEP—Continued

Code	Name of breed	Book of record	By whom published
4105	Kent or Romney Marsh	Kent or Romney Marsh Flock Book.	Kent or Romney Marsh Sheep-Breeders' Association, G. W. Tuffrey, secretary, Station Rd., Ashford, Kent, England.
4203	Kerry Hill	Kerry Hill Flock Book	Kerry Hill (Wales) Flock Society, Ralph P. Evans, secretary, c/o The Rednorshire Co., Ltd., Knighton, Radnorshire, Wales.
4106	Leicester	Leicester Flock Book	Leicester Sheep Breeders' Association, P. S. Atkinson, secretary, The Exchange, Exchange St., Driffield, E. Yorks., England.
4107	Lincoln	Flock Book of Lincoln Longwool Sheep.	Lincoln Longwool Sheep Breeders' Association, Brian Shelley, secretary, Westminster Bank Chambers, 8 Guildhall St., Lincoln, England.
4204	Oxford Down	Flock Book of Oxford Down Sheep.	Oxford Down Sheep Breeders' Association, Mrs. L. I. Deacon, secretary, Thornyfields, Billing Rd., Brafield-on-the-Green, Northampton, England.
4108	Romney Marsh	New Zealand Romney Marsh Flock Book.	New Zealand Romney Marsh Sheep Breeders' Association, Inc., R. J. J. Campbell, secretary, 117 Kimbolton Rd., Feilding, New Zealand.
4205	Ryeland	Ryeland Flock Book	Ryeland Flock Book Society, Ltd., P. J. Hoskins, secretary, 20 King St., Hereford, England.
4206	Shropshire	Shropshire Flock Book	Shropshire Sheep Breeders' Association and Flock Book Society, Ivor Guy Mansell, secretary, College Hill, Shrewsbury, Shropshire, England.
4207	Southdown	Southdown Flock Book	Southdown Sheep Society, Inc., R. G. Noakes, secretary, Westways, Barming Woods, Maidstone, Kent, England.
4218	......do	Southdown Sheep Society of New Zealand (Inc.).	The Southdown Sheep Society of New Zealand (Inc.), S. I. McKenzie, secretary, A.M.P., Chambers, 14 Broadway, Palmerston North, New Zealand.
4208	Suffolk	Suffolk Flock Book	Suffolk Sheep Society, Harry A. Byford, secretary, 30 Museum St., Ipswich, Suffolk, England.
4109	Wensleydale	Wensleydale Longwool Sheep Flock Book.	The Wensleydale Longwool Sheep Breeders' Association, W. Dickinson, secretary, "Cartmel," Church Walk, Ulverston, Lancashire, England.
4001	Various recognized breeds.	Flock Book for British Breeds of Sheep in Australia.	Australian Society of Breeders of British Sheep, H.T.C. Woodfull, secretary, Royal Show Grounds, Epsom Rd., Ascot Vale, W. 2, Victoria, Australia.
4002	......do	New Zealand Flock Book	New Zealand Sheep Breeders' Association, H.M. Studholme, secretary, P.O. Box 9002, Addington, Christchurch, New Zealand.

GOATS

Code	Name of breed	Book of record	By whom published
5001	Saanen and Toggenburg.	British Goat Society Herd Book (Saanen and Toggenburg Sections).	British Goat Society, Miss M.F. Rigg, secretary, Diss, Norfolk, England.

SWINE

Code	Name of breed	Book of record	By whom published
6001	Irish Large White	Herd Book of Irish Large White Pigs.	Royal Dublin Society, Horace H. Poole, registrar, Ball's Bridge, Dublin, Ireland.
6002	Berkshire Gloucestershire Old Spots Large Black Large White Middle White	Herd Book of the National Pig Breeders' Association.	National Pig Breeders' Association, E.G. Wake, secretary, 69 Clarendon Rd., Watford, Herts, England

SWINE—Continued

Code	Name of breed	Book of record	By whom published
	Tamworth British Saddleback		

DOGS

Code	Name of breed	Book of record	By whom published
7306	Australian Kelpie	The Working Kelpie Council National Stud Book.	The Working Kelpie Council, P.O. Box E31 St. James, Sidney 2000, Australia.
7301	Boxer	Boxer-Zuchtbuch	Boxer-Klub e. V. Sitz Munchen, Bernhard Schmitz, Prasident, 38 Otkerstrasse, Munchen 9, Germany.
7201	Dachshund	Teckel-Stammbuch	Deutscher Teckelklub e. V., Josef Chateau, Stammbuchfuhrer, Vallendar/Rhein, Haus Rheinnieder, Germany.
7202	Foxhound	Foxhound Kennel Stud Book	Masters of Foxhounds Association, Lt. Col. J. E. S. Chamberlayne, Hon. secretary, 51 Victoria St., London, S. W. 1, England.
7203	......do	Welsh Hound Stud Book	Welsh Hound Association, Islwyn E. E. Davies, Hon. secretary, Berthddu, Llandinam, Montgomeryshire, East Wales.
7302	German Shepherd	Zuchtbuch fur deutsche Schaferhunde (SZ).	Verein fur deutsche Schaferhunde (SV), Hann Kremheimer, Hauptgeschaftsfuhrer, Beim Schnarrbrunnen 4, Augsburg 5, Germany.
7303	Great Dane	Zuchtbuch fur Deutsche Doggen	Deutscher Doggen-Club, Richard Staadt, Prasident, Eilerstrasse 25, Solingen-Ohligs, Germany.
7204	Greyhound	Australian Greyhound Stud Book	The Australian and New Zealand Greyhound Association, Robert John Maidment, secretary, 349 Collins St., Melbourne, C. 1, Australia.
7205	......do	Greyhound Stud Book	National Coursing Club, Sydney H. Dalton, secretary, College Hill Chambers, London, E.C. 4. England.
7206	......do	Irish Greyhound Stud Book	Irish Coursing Club, Miss K. Butler, secretary, Davis Rd., Clonmel, Co. Tipperary, Ireland.
7207	Harrier and Beagle	Harrier and Beagle Stud Book	Association of Masters of Harriers and Beagles, J. J. Kirkpatrick, Hon. secretary, East Wing, Kirtlington Park, Oxford, England.
7304	Rottweiler	Zucht- und Korbuch	Allgemeiner Deutscher Rottweiler-Klub, Mrs. Josephine Rieble, Sekretarin, Vorsteigstrasse 5, Stuttgart-West, Germany.
7305	St. Bernard	Bernhardiner-Zuchtbuch	St. Bernhardsklub e. V., Franz Hrachowina, Zuchtbuchfuhrer, Bergmannstrasse 35, Munchen 12, Germany.
7001	Various recognized breeds.	Irish Kennel Club Stud Book	Irish Kennel Club, Miss Maud C. Fox, secretary, 23 Eden Quay, Dublin, C. 8, Ireland.
7002	......do	Kennel Club Stud Book	English Kennel Club, E. Holland Buckley, secretary, 1-4 Clarges St., Piccadilly, London, W. 1, England.
7003	......do	Livre des Origines Francais	Societe 1 Centrale Canine pour l'Amelioration des Races de Chiens en France, Col. Raoul Nicole, Directeur Administrateur, 3 Rue de Choiseul, Paris 2, France.
7004	......do	Livre des Origines de la Societe 1 Royale Saint-Hubert.	Societe 1 Royale Saint-Hubert, R. Willocq, Secretaire 1, 391 Chaussee Saint-Pierre, Brussels 4, Belgium.
7005	......do	Norsk Kennelklubs Stambok	Norsk Kennel Klub, Olaf A. Roig, secretary, Bjorn Farmannegate 16, Oslo, Norway.
7006	......do	Zuchtbuch des Klub fur Terrier e. V.	Klub fur Terrier e.V., Wilhelm Vahle, Sekretar, Schone Aussicht 9, Kelsterbach b. Frankfurt/Main, Germany.
7007	......do	Schweizerisches Hunde-Stammbuch.	Schweizerische Kynologischen Gesellschaft, Carl Wittwer, secretary, Seestrasse 64, Kilchberg/Zurich, Switzerland.
7008	......do	Svenska Kennelklubbens Register.	Svenska Kennelklubben, Ivan Swedrup, secretary, Linnegatan 25, Stockholm O 4, Sweden.

CATS

Code	Name of breed	Book of record	By whom published
8001	Long-haired and short-haired.	The Governing Council of the Cat Fancy Stud Book.	The Governing Council of the Cat Fancy, W.A. Hazeldine, secretary, 1 Roundwood Way, Banstead, Surrey, England.

(b) *Breeds and books of record in Canada*—(1) *Animals generally.* The books of record of the Canadian National Live Stock Records, Ottawa, Canada, of which F. G. Clark is Director, are recognized for the following breeds: *Provided,* That no animals registered in the Canadian National Live Stock Records shall be certified under the act as purebred unless such animals trace only to animals which are proved to the satisfaction of Veterinary Services to be of the same breed: *Provided further,* That no Dexter cattle, Karakul sheep, Alpine goat, Nubian goat, or horse of the American Saddle Horse, Arabian, Canadian, Morgan, Shetland Pony or Welsh Pony and Cob breed in Canada shall be certified under the act as purebred unless a pedigree certificate showing three complete generations of known and recorded purebred ancestry of the particular breed involved, issued by the Canadian National Live Stock Records, is submitted for such animal.

Code	Name of breed	Code	Name of breed
	CATTLE		
1108	Aberdeen, Angus.		
1210	Ayrshire.	1111	Highland.
1211	Brown Swiss.	1214	Jersey.
1212	Canadian.	1311	Lincoln Red.
1310	Dexter.	1312	Red Poll.
1109	Galloway.	1313	Shorthorn.
1213	Guernsey.		
	HORSES		
2227	American Saddle Horse.	2109	Percheron.
2228	Arabian.	2304	Shetland Pony.
2107	Belgian Draft.	2110	Shire
			Suffolk.
2229	Canadian.	2111	Thoroughbred.
2108	Clydesdale.	2232	Welsh Pony.
2230	Hackney.	2305	and Cob.
2236	Morgan.		
	SHEEP		
4110	Blackface.	4115	Lincoln.
4111	Cheviot.	4116	Merino.
4112	Corriedale.	4213	Oxford Down.
4113	Cotswold.	4117	Rambouillet.
4209	Dorset Horn.	4214	Ryeland.
4210	Hampshire.	4215	Shropshire.
4211	Karakul.	4216	Southdown.
4212	Kerry Hill.	4217	Suffolk.
4114	Leicester.		
	GOATS		
5002	Alpine. Angora. Nubian. Saanen. Toggenburg.		
	SWINE		
6003	Berkshire. Chester White. Duroc-Jersey. Hampshire. Lacombe. Landrace. Large Black. Poland China. Tamworth. British Saddleback. Yorkshire.		

(2) *Holstein-Friesian cattle in Canada (Code 1215).* The Holstein-Friesian Association of Canada, Brantford, Ontario, Canada, of which G. M. Clemons is secretary and editor, is recognized for the Holstein-Friesian breed registered in the Holstein-Friesian Herd Book of that Association.

(3) *Dogs in Canada (Code 7009).* The Stud Book of the Canadian Kennel Club, Incorporated (Canadian National Live Stock Records) is recognized for all the breeds of dogs registered therein: *Provided,* That no dog so registered shall be certified under the act as purebred unless a pedigree certificate showing three complete generations of known and recorded purebred ancestry of the particular breed involved, issued by the Canadian Kennel Club, Incorporated, is submitted for such dog.

(4) *Standardbred horses in Canada (Code 2231).* The Canadian Standard

Bred Stud Book kept by the Canadian Standard Bred Horse Society, 122 Brown's Line, Toronto 14, Ontario, Canada, is recognized for all Standardbred horses registered therein: *Provided,* That no Standard bred so registered shall be certified under the act as purebred unless a pedigree certificate showing three complete generations of known and recorded purebred Standardbred ancestry, issued by the Canadian Standard Bred Horse Society, is submitted for each such horse.

(5) *Charolais cattle in Canada (Code 1112).* The full French book of record of the Canadian Charolais Association, Calgary, Alberta, Canada, is recognized for the Charolais breed registered therein.

(6) *Maine-Anjou cattle in Canada (Code 1113).* The full French book of record of the Canadian Maine-Anjou Association, which is maintained by the Canadian National Live Stock Records, is recognized for the Maine-Anjou breed registered in the Canadian Maine-Anjou Herd Book: *Provided,* That no Maine-Anjou cattle so registered shall be certified under the act as purebred unless a pedigree certificate showing at least three generations of known and recorded purebred ancestry of the breed involved, issued by the Canadian National Live Stock Records, is submitted for each such animal.

(7) *Simmental cattle in Canada (Code 1114).* The Canadian Simmental Association, Calgary, Alberta, Canada, of which Mr. John Kish is Executive Secretary, is recognized for the Simmental breed registered in the Canadian Simmental Association Full Blood Herd Book: *Provided,* That no simmental cattle so registered shall be certified under the act as purebred unless a pedigree certificate showing at least three generations of known and recorded purebred ancestry of the breed involved, issued by the Canadian Simmental Association is submitted for each such animal.

(8) *Hereford cattle in Canada (Code 1110).* The Canadian Hereford Herd Book of The Canadian Hereford Association, 5160 Skyline Way NE., Calgary, Alberta, Canada, of which Dr. Duncan J. Porteous is General-Manager, is recognized for the Hereford breed registered therein.

(Sec. 101, 76 Stat. 72, Item 100.01, Title I, Tariff Act of 1930, as amended; 19 U.S.C. 1202, Item 100.01; 7 CFR 2.17, 2.51, and 371.2(d))

[23 FR 10104, Dec. 23, 1958]

EDITORIAL NOTE: For Federal Register citations affecting § 151.9, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 151.10 Recognition of additional breeds and books of record.

Before a breed or a book of record shall be added to those listed in this part, the custodian of the book of record involved shall submit to Veterinary Services a complete copy of the book of record, consisting of any published printed volumes and any microfilm records issued by the registry association up to date of application, together with a copy of all rules and forms in force on said date affecting the registration of animals in said book.

[24 FR 2644, Apr. 7, 1959]

§ 151.11 Form of books of record.

(a) If a registry association has not published its book of record in printed form, a record in approved microfilm form which the Deputy Administrator, Veterinary Services finds provides a system for determining the recorded

[24 FR 2644, Apr. 7, 1959]

ancestry of the animals identified therein will be acceptable. When a registry association which has published its book of record in printed form ceases such publication and in lieu thereof publishes a microfilm record, the microfilm record shall commence with the first pedigree recorded by the association which is not in the printed volumes and shall otherwise be in approved form.

(b) A microfilm record will be approved under this part only if it is 16 mm. non-perforated safety film exposed at a reduction ratio not to exceed 24 diameters. All information on the original document shall be reproduced onto the microfilm so that it is clearly readable. The microfilm carton shall be indexed to state the numbers of the pedigree certificates on the roll of film it contains.

[24 FR 2644, Apr. 7, 1959]

SUBCHAPTER H—VOLUNTARY INSPECTION AND CERTIFICATION SERVICE

PART 156—INSPECTION AND CERTIFICATION OF ANIMAL BYPRODUCTS

Sec.
156.1 Meaning of words.
156.2 Definitions.
156.3 Kind of service; records.
156.4 Application for service.
156.5 Availability of service.
156.6 Certificates.
156.7 Fees and charges.
156.8 Refusal of service; denial or withdrawal of service.

AUTHORITY: Secs. 203, 205, 60 Stat. 1087, 1090; 7 U.S.C. 1622, 1624.

SOURCE: 23 FR 10111, Dec. 23, 1958, unless otherwise noted.

EDITORIAL NOTE: For nomenclature changes see, 36 FR 24928, Dec. 24, 1971.

§ 156.1 Meaning of words.

Words used in this part in the singular form shall import the plural, and vice versa, as the case may demand.

§ 156.2 Definitions.

For the purposes of this part, unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

(a) *Department.* The United States Department of Agriculture.

(b) *Administrator.* The Administrator of the Animal and Plant Health Inspection Service of the Department, or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated to act in his stead.

(c) *Deputy Administrator.* The Deputy Administrator, Veterinary Services unit of the Animal and Plant Health Inspection Service of the Department, or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

(d) *Inspector.* Any officer or employee of the Department of cooperating agency authorized to perform any duties under a cooperative agreement at any plant furnished service under this part.

(e) *Inspector in charge.* An inspector of the Department assigned by the Deputy Administrator to supervise, review, and perform official work pertaining to a plant furnished service under this part.

(f) *Person.* Any individual, corporation, company, association, firm, partnership, society, joint stock company, or other form of organization.

(g) *Applicant.* Any person who requests service under this part.

(h) *Animal byproducts.* Any inedible part, or combination of inedible parts of carcasses of livestock or poultry, processed by cooking, curing, drying, or other methods acceptable to the trade, including but not limited to tankage, blood meal, bones, bone meal, hides, skins, wool, and hair.

(i) *Cooperative agreement.* An agreement, between the Department and some other Federal or State agency, board of trade, chamber of commerce, or other agency, association, organization, person, or corporation as provided for in section 205 of the Agricultural Marketing Act of 1946 (7 U.S.C. 1624), to conduct cooperatively service under this part.

§ 156.3 Kind of service; records.

Laws, regulations or other requirements of foreign countries and specifications of contracts for the purchase and sale of animal byproducts, on occasion require vendors of such byproducts to furnish official certificates concerning the class, quality, quantity, or condition of such byproducts to be imported into such countries or to be delivered under the contracts. The service under this part, shall consist of the inspection of the processing, handling, and storage of the byproducts at any plant at which service is furnished and the certification, on the basis of such requirements of foreign countries or such contract specifications, of the class, quality, quantity, or condition of such of the byproducts as are found to conform to such requirements or specifications as the case may be. Processing procedures will be actually supervised. The operator of the plant shall fully inform the inspector with respect to, and the inspector shall actually observe, the processing procedures, handling, and storage of the byproducts intended for certification. The inspector shall keep such records of the temperatures reached, the duration of time the temperatures are maintained, and the pounds of pressure under which the byproducts are cooked in the course of processing, and such other information, as are needed to justify the issuance of the certificates required.

§ 156.4 Application for service.

Any person who is eligible under a cooperative agreement to receive service under this part may apply therefor to the Deputy Administrator, upon an application form which will be furnished by the Deputy Administrator upon request. The application form shall require the applicant to state, among other things, the forms of certificates desired.

(Approved by the Office of Management and Budget under control number 0579-0008)

[23 FR 10111, Dec. 23, 1958, as amended at 48 FR 57473, Dec. 30, 1983]

§ 156.5 Availability of service.

Subject to § 156.8, service under this part will be furnished, upon application, within the limits of available Department personnel and facilities, at any plant the operator of which applies for or endorses the application for the service if the Deputy Administrator finds that: the forms of certificates desired by the applicant require the certification of class, quality, quantity, or condition; the plant and its methods of processing, handling and storage of the byproducts intended for certification are adequate to warrant the issuance of the desired certificates; service is to be furnished under a cooperative agreement; and the requirements of § 156.7 are met.

§ 156.6 Certificates.

The inspector shall sign and issue certificates in forms approved by the Deputy Administrator for animal byproducts inspected in accordance with this part, if he finds that the requirements as stated in the certification have been met. The original and one copy of each certificate shall be furnished to the applicant, and one copy of each certificate shall be retained by the Department until disposal is authorized in accordance with law. Additional copies may be furnished the applicant at his request upon payment of the fees prescribed in § 156.7. Copies of the certificates may be furnished without charge to other properly interested Federal agencies or under compulsory process.

§ 156.7 Fees and charges.

Fees and charges for service (including travel and other expenses incurred in connection with the furnishing of service) under this part shall be paid by the applicant in accordance with the terms of the cooperative agreement under which service is furnished and in accordance with this section which shall be deemed to be incorporated in such agreement. If required by the Administrator, the fees and charges shall be paid in advance. Since the fees and charges are for the purpose of reimbursing the Department for all costs incurred in connection with the furnishing of service under this part, the appropriate fees and charges to cover any such costs shall be paid even though service is withheld pursuant to § 156.8.

§ 156.8 Refusal of service; denial or withdrawal of service.

(a) Service under this part will be refused if the conditions stated in §§ 156.5 and 156.6 are not met.

(b) Service under this part may be withdrawn from, or denied to, any applicant by the Administrator, for such period as the Administrator may prescribe, when the Administrator is satisfied, after opportunity for hearing before a proper official has been accorded the applicant, that the applicant or other operator of the plant where service has been or would be furnished under the application, or the agent or employee of such applicant or operator within the scope of his employment, has persistently failed to give the inspector full and correct information with respect to the processing procedures, handling, and storage of animal byproducts intended for certification or certified; or has given to any employee of the Department false information in connection with service under this part; or has altered or imitated any certificate, mark, or device provided for under this part; or has used any such certificate, mark, or device without authority from the Deputy Administrator, or any imitation of any such certificate, mark, or device, on or with respect to any animal byproducts; or has knowingly and without promptly notifying the Deputy Administrator retained possession of any such device or imitation thereof or altered or imitation certificate or of any animal byproducts marked with any such device without authority from the Deputy Administrator or marked with any imitation of such device; or has given or attempted to give, for any purpose whatsoever, any money, favor, or other thing of value, to any employee of the Department authorized to perform any function under this part; or has interfered with or obstructed, or attempted to interfere with or to obstruct, any employee of the Department in or with respect to the performance of his duties under this part by intimidation, threats, assaults, or any other improper means. The inspector assigned to any plant may suspend service at such plant for any of the reasons set forth in this paragraph, without hearing, and in that event shall report his actions to the Deputy Administrator, and the Deputy Administrator may continue such suspension or otherwise deny or suspend service at any plant for any of such reasons, without hearing, pending final disposal of the matter under this paragraph.

(c) All final orders in any proceeding to deny or withdraw the service for any of the reasons set forth in paragraph (b) of this section (except orders required for good cause to be held confidential and not cited as precedents) shall be filed with the Hearing Clerk of the Department and be available to public inspection.

SUBCHAPTER I—ACCREDITATION OF VETERINARIANS AND SUSPENSION OR REVOCATION OF SUCH ACCREDITATION

PART 160—DEFINITION OF TERMS

§ 160.1 Definitions.

For the purposes of this subchapter the following words, phrases, names, and terms shall be construed, respectively, to mean:

(a) *"Service."* The Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

(b) *"Deputy Administrator."* The Deputy Administrator for the Service or his representative to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(c) *"State."* Any State, Territory, the District of Columbia or the Commonwealth of Puerto Rico.

(d) *"Accredited Veterinarian."*[1] A veterinarian approved by the Deputy Administrator in accordance with the provisions of Part 161 of this subchapter to perform functions specified in Parts 1, 2, 3, and 11 of Subchapter A, and Subchapters B, C, and D of this chapter, and to perform functions required by cooperative State-Federal disease control and eradication programs.

(e) *"Veterinarian-in-Charge."* The veterinary official of the Service who is assigned by the Deputy Administrator to supervise and perform the official work of the Service in the State where the veterinarian concerned is accredited or wishes to be accredited.

(f) *"State Animal Health Official."* The State Animal Health Official who is responsible for the livestock and poultry disease control and eradication programs of the State in which the veterinarian is accredited or wishes to be accredited.

(g) *"Official certificate, form, record, report, tag, band, brand, or other identification."* Means any certificate, form, record, report, tag, band, brand, or other identification, prescribed by statute or regulations issued by the Secretary of Agriculture of the United States or State Animal Health Official, for issuance by an accredited veterinarian performing official functions under this subchapter.

(h) *"Secretary."* The Secretary of Agriculture or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

(23 Stat. 32, as amended; 58 Stat. 734, as amended; 65 Stat. 693; 26 Stat. 417; 32 Stat. 791, 792, as amended; 33 Stat. 1265, as amended; 34 Stat. 1263, 1264; 41 Stat. 241; 41 Stat. 699; 65 Stat. 693; 76 Stat. 130, 132; 84 Stat. 1406; 15 U.S.C. 1828; 21 U.S.C. 80-86, 89, 96, 105, 111-113, 114, 114a, 114a-1, 115, 116, 120, 121, 125, 134b, 134f)

[39 FR 23050, June 26, 1974, as amended at 42 FR 41850, Aug. 19, 1977; 44 FR 63493, Nov. 11, 1979]

PART 161—REQUIREMENTS AND STANDARDS FOR ACCREDITED VETERINARIANS AND SUSPENSION OR REVOCATION OF SUCH ACCREDITATION

Sec.
161.1 Requirements for accreditation.
161.2 Standards for accredited veterinarians.
161.3 Suspension or revocation of veterinary accreditation.

AUTHORITY: 23 Stat. 32 as amended; 26 Stat. 417; 32 Stat. 791, 792, as amended; 33 Stat. 1265, as amended; 41 Stat. 699; 58 Stat. 734, as amended; 65 Stat. 693; 76 Stat. 130, 132; 84 Stat. 1406; 15 U.S.C. 1828; 21 U.S.C. 105, 111-114, 114a, 114a-1, 116, 120, 121, 125, 134b and 134f.

SOURCE: 39 FR 23050, June 26, 1974, unless otherwise noted.

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[1] The provisions of Part 11 of Subchapter A, and Subchapters B, C, and D of this chapter authorize Federal and State veterinarians and accredited veterinarians to perform specified functions. Full-time Federal (including military and State employed veterinarians are authorized to perform such functions, pursuant to delegation of authority or cooperative agreements without specific accreditation under the provisions of this subchapter.

§ 161.1 Requirements for accreditation.

(a) The Deputy Administrator is hereby authorized to accredit a veterinarian when he determines that such veterinarian (1) is a graduate of a college of veterinary medicine; (2) is licensed to practice veterinary medicine in the State in which he wishes to be accredited; (3) has made formal application for accreditation on Form 1-36A, "Application for Veterinary Accreditation"; (4) has passed an examination administered by the Service; and (5) has been jointly recommended by the State Animal Health Official and the Veterinarian-in-Charge for the State in which the veterinarian is licensed and wishes to be accredited.

(b) The Deputy Administrator is hereby authorized to reaccredit a veterinarian whose accreditation has been revoked when he determines, after the order of revocation has been in effect for not less than one year, that such veterinarian (1) is licensed to practice veterinary medicine in the State in which he wishes to be accredited; (2) has made formal application for accreditation on Form I-36A, "Application for Veterinary Accreditation"; (3) has been jointly recommended by the State Animal Health Official and the Veterinarian-in-Charge for the State in which the veterinarian is licensed and wishes to be accredited; and (4) such veterinarian has furnished adequate assurance that he will faithfully fulfill the duties of an accredited veterinarian in the future.

(Approved by the Office of Management and Budget under control number 0579-0032)

[39 FR 23050, June 26, 1974, as amended at 48 FR 57474, Dec. 30, 1983]

§ 161.2 Standards for accredited veterinarians.

An accredited veterinarian shall perform official duties subject to the supervision and direction of the Veterinarian-in-Charge and the State Animal Health Official and shall observe the following specific standards:

(a) An accredited veterinarian shall not issue a certificate, form, record or report which reflects the results of any inspection, test, vaccination or treatment performed by him, with respect to any animal or poultry, unless he has personally inspected each animal, bird, or flock in such a manner as to detect abnormalities, such as, but not limited to, locomotion, body excretion, respiration, and skin conditions. An accredited veterinarian shall thoroughly examine each animal, bird, or flock showing abnormalities, in order to determine whether or not there is the presence or absence of a communicable disease, or in the case of a horse being examined under Part 11 of Subchapter A, whether or not it complies with such regulations and the provisions of the Horse Protection Act of 1970, and any legislation amendatory thereof.

(b) An accredited veterinarian shall not sign any certificate, form, record or report, or permit such a certificate, form, record, or report to be used until, and unless, he has ascertained that it has been accurately and fully completed clearly identifying the animal(s) or bird(s) to which it applies and showing the results of the inspection, test, or vaccination, etc., he has conducted, except as provided in paragraph (c) of this section. An accredited veterinarian shall not sign any certificate provided for by the Animal Welfare Act or its regulations and standards unless he has ascertained that the statements contained therein are complete, clear and accurate. The accredited veterinarian shall distribute copies of certificates, forms, records and reports, according to instructions issued to him by the Veterinarian in Charge or the State Animal Health Official.

(c) An accredited veterinarian shall not issue or sign any certificate, form, or report which reflects the results of any inspection, test, vaccination, or treatment, performed by another accredited veterinarian, unless the certificate, form, or report indicates that the inspection, test, vaccination, or treatment was performed by the other veterinarian; identifies the name of such other veterinarian; and includes the date and the place where such inspection, test, or vaccination was performed.

(d) An accredited veterinarian shall perform official tests, inspections, treatments, and vaccinations and shall submit specimens to designated laboratories in accordance with Federal and State regulations and instructions issued to the accredited veterinarian by the Veterinarian-in-Charge or the State Animal Health Official, or both.

(e) An accredited veterinarian shall identify reactor animals by branding and tagging or such other method as may be prescribed in instructions issued to him by the Veterinarian-in-Charge or the State Animal Health Official, or both.

(f) An accredited veterinarian shall immediately report all diagnosed or suspected cases of diseases of livestock, birds, or poultry named in § 71.3(a) and (b) of Part 71, Subchapter C of this chapter, to the Veterinarian-in-Charge or the State Animal Health Official, or both. An accredited veterinarian designated to examine and observe horses at shows and exhibitions shall complete the form provided on all horses which he considers are sored and shall promptly report each horse considered by him to be sored to the Veterinarian-in-Charge for the State in which the horse show or exhibition is held in accordance with the Horse Protection Act of 1970, or any legislation amendatory thereto, and the regulations as promulgated in Part 11, Subchapter A of this chapter.

(g) An accredited veterinarian shall take such measures as are necessary to prevent the spread of communicable diseases of livestock or poultry. Such measures shall include, but are not limited to, the use of sanitized instruments to collect specimens from, or to administer vaccines to such individual animals, birds, or poultry, and the cleaning and disinfecting of footwear, restraining chutes, and other equipment before proceeding to another premises.

(h) An accredited veterinarian shall keep himself currently informed on Federal and State regulations governing the movement of animals and poultry, and on procedures applicable to disease control and eradication programs, including emergency programs, and on definitions, regulations, and standards under the Animal Welfare Act, and any legislation amendatory thereof, and on regulations under the Horse Protection Act of 1970, and any legislation amendatory thereof. He shall carry out all of his responsibilities under the applicable Federal programs and cooperative programs in accordance with such regulations and instructions issued to him by the Veterinarian in Charge or the State Animal Health Official, or both.

(i) An accredited veterinarian shall not use or dispense in any manner, any drug, chemical, vaccine or serum, or other biological product authorized, for use under any Federal regulation or cooperative disease eradication program, without authorization from the Service or in contravention of any Federal or State statute or regulation, or instruction.

(j) An accredited veterinarian shall be responsible for proper use of all certificates, forms, records, reports, tags, brands, bands, or other identification used in his work as an accredited veterinarian and shall take proper precautions to prevent misuse thereof. He shall immediately report to the Veterinarian-in-Charge or State Animal Health Official the loss, theft, or deliberate or accidental misuse of any such certificate, form, record, report, tag, band, brand, or other identification. He shall not permit any certificate, form, record, report, tag, band, brand, or other identification, to be kept in the custody of anyone but himself prior to official use.

(k) An accredited veterinarian designated under the regulations issued pursuant to the Horse Protection Act of 1970, and any legislation amendatory thereof (Part 11, Subchapter A, 9 CFR), for the purpose of determining whether horses are in compliance with said Act, and any legislation amendatory thereof, and said regulations, shall thoroughly examine each horse in a professionally acceptable manner, in accordance with any instructions given by the Veterinarian-in-Charge, to determine whether or not each horse is in compliance with said Act, and any legislation amendatory thereof, and said regulations.

[39 FR 23050, June 26, 1974, as amended at 44 FR 63494, Nov. 2, 1979]

§ 161.3 Suspension or revocation of veterinary accreditation.

(a) The Secretary is authorized to suspend for a given period of time, or to revoke, the accreditation of a veterinarian when he determines that the accredited veterinarian has not complied with the "Standards for Accredited Veterinarians" as set forth in § 161.2, or in lieu thereof to issue a written notice of warning to the accredited veterinarian when the Deputy Administrator determines a notice of warning will be adequate to attain compliance with the Standards.

(b) Accreditation in a given State shall be automatically terminated when an accredited veterinarian's license to practice veterinary medicine in that State is terminated.

(c) Accreditation shall be automatically revoked when an accredited veterinarian is convicted of a crime in either State or Federal court, if such conviction is based on the performance or nonperformance of any act required of him in his capacity as an accredited veterinarian.

(d) Any suspension or revocation of accreditation for failure to comply with the Standards shall be applicable in all States in which the veterinarian is accredited.

[39 FR 23050, June 26, 1974, as amended at 42 FR 41850, Aug. 19, 1977]

PART 162—RULES OF PRACTICE GOVERNING REVOCATION OR SUSPENSION OF VETERINARIANS' ACCREDITATION

Subpart A—General

Sec.
162.1 Scope and applicability of rules of practice.

Subpart B—Supplemental Rules of Practice

162.10 Summary suspension of accreditation of veterinarians.
162.11 Notification.
162.12 Informal conference.
162.13 Formal complaint.

Authority: 23 Stat. 32, as amended; 26 Stat. 417; 32 Stat. 791.792, as amended; 33 Stat. 1265, as amended; 41 Stat. 699; 56 Stat. 734; 65 Stat. 693; 84 Stat. 1406 (15 U.S.C. 1828; 21 U.S.C. 105, 111, 114a-1, 115, 116, 120, 121, 125, and 134f).

Source: 42 FR 10960, Feb. 25, 1977, unless otherwise noted.

Subpart A—General

§ 162.1 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the Department of Agriculture promulgated in Subpart H of Part 1, Subtitle A, Title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings for the revocation or suspension of accreditation of veterinarians (9 CFR Parts 160 and 161). In addition, the Supplemental Rules of Practice set forth in Subpart B of this part shall be applicable to such proceedings.

Subpart B—Supplemental Rules of Practice

§ 162.10 Summary suspension of accreditation of veterinarians.

In any situation where the Administrator has reason to believe that any veterinarian accredited under the provisions of 9 CFR Parts 160 and 161 has not complied with the "Standards for Accredited Veterinarians" set forth in 9 CFR 161.2, and he deems such action necessary in order to adequately protect the public health, interest, or safety, the Administrator may suspend the accreditation of such veterinarian pending final determination in the proceeding, effective upon oral or written notification, whichever is earlier. In the event of oral notification, a written confirmation thereof shall be given to such veterinarian pursuant to § 1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)) as promptly as circumstances permit. Such suspension shall have no relevance with respect to the final determination in the proceeding.

§ 162.11 Notification.

The Veterinarian in Charge shall notify the accredited veterinarian when there is reason to believe that he has not complied with the "Standards for Accredited Veterinarians" as contained in 9 CFR 161.2. The notification shall be in writing and shall include a statement of the basis for the belief that the accredited veterinarian has failed to comply with the standards and shall notify the accredited veterinarian of the desire of the Veterinarian in Charge to arrange an informal conference to discuss the matter.

§ 162.12 Informal conference.

(a) The Veterinarian in Charge, with the concurrence of the State Animal Health Official and the accredited veterinarian, shall designate the time and place for the holding of an informal conference to review the matter.

(b) If during, or at the conclusion of, the informal conference, the Veterinarian in Charge determines that a warning will be adequate to attain compliance with the standards, he may issue such warning in writing to the accredited veterinarian without further procedure.

(c) If prior to, during, or at the conclusion of, the informal conference, the accredited veterinarian consents, in writing, to the issuance of an order revoking or suspending his accreditation for a specified period of time, in lieu of further procedure, the Veterinarian in Charge may issue such an order without further procedure.

§ 162.13 Formal complaint.

If a consent order has not been issued, or if, after an informal conference, the Veterinarian in Charge has not issued a warning to the accredited veterinarian, a complaint in writing shall be issued by the Administrator in accordance with § 1.135 of the Uniform Rules of Practice (7 CFR 1.135).

SUBCHAPTER J—PUBLIC INFORMATION

PART 165—AVAILABILITY OF INFORMATION

§ 165.1 Availability of information.

The Animal and Plant Health Inspection Service regulations relating to availability of information to the public and disclosure of records under 5 U.S.C. 552, which are set forth in 7 CFR Part 370, are incorporated into this subchapter.

(5 U.S.C. 552, 559)

[32 FR 10915, July 26, 1967, as amended at 36 FR 24928, Dec. 24, 1971]

SUBCHAPTER K—SWINE HEALTH PROTECTION

PART 166—SWINE HEALTH PROTECTION

GENERAL PROVISIONS

Sec.
166.1 Definitions in alphabetical order.
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166.3 Separation of swine from the garbage handling and treatment areas.
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166.12 Licensee responsibilities.
166.13 Cleaning and disinfecting.
166.14 State status.

AUTHORITY: 7 U.S.C. 3802, 3803, 3804, 3808, 3809, 3811; 7 CFR 2.17, 2.51, and 371.2(d).

SOURCE: 47 FR 49945, Nov. 3, 1982, unless otherwise noted.

GENERAL PROVISIONS

§ 166.1 Definitions in alphabetical order.

For the purposes of this part, the following terms shall have the meanings assigned them in this section. Unless otherwise required by the context, the singular form shall also import the plural and the masculine form shall also import the feminine, and vice versa. Words undefined in the following paragraphs shall have the meaning attributed to them in general usage as reflected by definitions in a standard dictionary.

Act. The Swine Health Protection Act (Pub. L. 96-468) as amended by the Farm Credit Act Amendments of 1980 (Pub. L. 96-592).

Administrator. The Administrator of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), or any other official to whom authority has heretofore been delegated or to whom authority may hereafter be delegated to act in his stead.

Animal and Plant Health Inspection Service (APHIS). Animal and Plant Health Inspection Service, United States Department of Agriculture.

Animals. All domesticated and wild mammalian, poultry, and fish species, and wild and domesticated animals, including pets such as dogs and cats.

Area Veterinarian in Charge. The veterinarian of Veterinary Services who is assigned by the Deputy Administrator to supervise and perform the official work of Veterinary Services in a State or States or any other official to whom authority has heretofore been delegated or to whom authority may hereafter be delegated to act in his stead.

Birds. All domesticated and wild avian species.

Department. The United States Department of Agriculture (USDA).

Deputy Administrator. The Deputy Administrator for Veterinary Services or any other official to whom authority has heretofore been delegated or to whom authority may hereafter be delegated to act in his stead.

Facility. The site and all objects at this site including equipment and structures where garbage is accumulated, stored, handled, and cooked as a food for swine and which are fenced in or otherwise constructed so that swine are unable to have access to untreated garbage.

Garbage. All waste material derived in whole or in part from the meat of any animal (including fish and poultry) or other animal material, and other refuse of any character whatsoever that has been associated with any such material, resulting from the handling, preparation, cooking or consumption of food, except that such term shall not include waste from ordinary household operations which is fed directly to swine on the same premises where such household is located.

Inspector. Any inspector or veterinarian employed by the Department or by the State for the purposes of enforcing the Act and this Part.

License. A permit issued to a person for the purpose of allowing such person to operate a facility to treat garbage that is to be fed to swine.

Licensee. Any person licensed pursuant to the Act and regulations.

Person. Any individual, corporation, company, association, firm, partnership, society or joint stock company or other legal entity.

Premises. The location of a garbage treatment facility, as defined in this part, and any areas owned or controlled by the operator of the facility where swine are kept or fed by the operator.

Rendered product. Waste material derived in whole or in part from the meat of any animal (including fish and poultry) or other animal material, and other refuse of any character whatsoever that has been associated with any such material, resulting from the handling, preparation, cooking or consumption of food that has been ground and heated to a minimum temperature of 230° F. to make products such as, but not limited to, animal, poultry, or fish protein meal, grease or tallow.

State. The fifty States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands of the United States, American Samoa, the Commonwealth of the Northern Mariana Islands, and the territories and possessions of the United States.

State animal health official. The State animal health official responsbile for livestock and poultry disease control and eradication programs or any other official to whom authority has heretofore been delegated or to whom authority may hereafter be delegated to act in his stead.

Treated garbage. Edible waste for animal consumption derived from garbage (as defined in this section) that has been heated throughout at boiling or equivalent temperature (212° F. or 100° C. at sea level) for 30 (thirty) minutes under the supervision of a licensee.

Treatment. The heating of garbage to specifications as set forth in this part.

Untreated garbage. Garbage that has not been treated in accordance with the Act and these regulations.

Veterinary Services. The unit of the Animal and Plant Health Inspection Service which is assigned responsibility for the performance of functions under the Act.

(Sec. 511, Pub. L. 96-592, 94 Stat. 3451 (7 U.S.C. 3802); secs. 4, 5, 9, 12, Pub. L. 96-468, 94 Stat. 2229 (7 U.S.C. 3803, 3804, 3808, 3811) 7 CFR 2.17, 2.51, and 371.2(d))

[47 FR 49945, Nov. 3, 1982, as amended at 48 FR 22290, May 18, 1983]

§ 166.2 General restrictions.

(a) No person shall feed or permit the feeding of garbage to swine unless the garbage is treated to kill disease organisms, pursuant to this Part, at a facility operated by a person holding a valid license for the treatment of garbage; except that the treatment and license requirements shall not apply to the feeding or the permitting of the feeding to swine of garbage only because the garbage consists of any of the following: rendered products; bakery waste; candy waste; eggs; domestic dairy products (including milk); fish from the Atlantic Ocean within 200 miles of the continental United States or Canada; or fish from inland waters of the United States or Canada which do not flow into the Pacific Ocean.

(b) No person operating such a facility may be licensed to treat garbage unless he or she meets the requirements of this part designed to prevent the introduction of dissemination of any infectious or communicable disease of animals and unless the facility is so constructed that swine are unable to have access to untreated garbage or equipment and material coming in contact with untreated garbage.

(c) The regulations of this part shall not be construed to repeal or supersede State laws that prohibit feeding of garbage to swine or to prohibit any State from enforcing requirements relating to the treatment of garbage that is to be fed to swine or the feeding thereof which are more stringent than the requirements contained in this part. In a State which prohibits the feeding of garbage to swine, a Federal license under the Act will not be issued to any applicant.

(Sec. 511, Pub. L. 96-592, 94 Stat. 3451 (7 U.S.C. 3802); secs. 4, 5, 9, 10, 12, Pub. L. 96-468, 94 Stat. 2229-2233 (7 U.S.C. 3803, 3804, 3808, 3809, 3811) 7 CFR 2.17, 2.51, and 371.2(d))

[47 FR 49945, Nov. 3, 1982, as amended at 49 FR 14497, Apr. 12, 1984]

§ 166.3 Separation of swine from the garbage handling and treatment areas.

(a) Access by swine to garbage handling and treatment areas shall be prevented by construction of facilities to exclude all ages and sizes of swine.

(b) All areas and drainage therefrom, used for the handling and treatment of untreated garbage shall be inaccessible to swine on the premises. This shall include the roads and areas used to transport and handle untreated garbage on the premises.

§ 166.4 Storage of garbage.

(a) Untreated garbage at a treatment facility shall be stored in covered and leakproof containers until treated.

(b) Treated garbage shall be transported to a feeding area from the treatment facility only in (1) containers used only for such treated garbage; (2) containers previously used for garbage which have been cleaned and disinfected in accordance with § 166.13 of this part; or (3) containers in which the garbage was treated.

§ 166.5 Licensed garbage-treatment facility standards.

Garbage-treatment facilities shall be maintained as set forth in this section.

(a) Insects and animals shall be controlled. Accumulation of any material at the facility where insects and rodents may breed is prohibited.

(b) Equipment used for handling untreated garbage, except for the containers in which the garbage has been treated, may not be subsequently used in the feeding of swine unless first cleaned and disinfected as set forth in § 166.13(b).

(c) Untreated garbage that is not to be fed to swine and materials in association with such garbage shall be disposed of in a manner consistent with all applicable governmental environmental regulations and in an area inaccessible to swine.

§ 166.6 Swine feeding area standards.

Untreated garbage shall not be allowed into swine feeding areas. Any equipment or material associated with untreated garbage, except for containers holding treated garbage which was treated in such containers, shall not be allowed into swine feeding areas at treatment premises until properly cleaned and disinfected as set forth in § 166.13(b).

§ 166.7 Cooking standards.

(a) Garbage shall be heated throughout at boiling (212° F. or 100° C. at sea level) for 30 (thirty) minutes.

(b) Garbage shall be agitated during cooking, except in steam cooking equipment, to ensure that the prescribed cooking temperature is maintained throughout the cooking container for the prescribed length of time.

§ 166.8 Vehicles used to transport garbage.

Vehicles used by a licensee to transport untreated garbage, except those that have also been used to treat the garbage so moved, shall not be used for hauling animals or treated garbage until cleaned and disinfected as set forth in § 166.13(c).

§ 166.9 Recordkeeping.

(a) Each licensee shall record the destination and date of removal of all treated or untreated garbage removed from the licensee's premises.

(b) Such records shall be legible and indelible.

(c) Each entry in a record shall be certified as correct by initials or signature of the licensee or an authorized agent or employee of the licensee.

(d) Such records shall be maintained by the licensee for a period of 1 (one) year from the date made and shall be made available to inspectors upon request during normal business hours at that treatment facility.

(Approved by the Office of Management and Budget under control number 0579-0066)

[47 FR 49945, Nov. 3, 1982, as amended at 48 FR 57474, Dec. 30, 1983]

§ 166.10 Licensing.

(a) *Application.* Any person operating or desiring to operate a treatment facility for garbage that is to be treated and fed to swine shall apply for a license on a form which will be furnished, upon request, by the Area Veterinarian in Charge or, in States with primary enforcement responsibility, by the State animal health official in the State in which the person operates or intends to operate. When a person operates more than one treatment facility, a separate application to be licensed shall be made for each facility. Exemptions to the requirements of this paragraph may be granted in States other than those with primary enforcement responsibility by the Deputy Administrator, if he finds that there would not be a risk to the swine industry in the United States. Any person operating or desiring to operate a facility to treat garbage to be fed to swine who would otherwise be required under this part to obtain a license to treat garbage only because it contains one or more of the items allowed to be fed to swine under § 166.2(a) is exempted from the requirements of this paragraph.

(b) *Acknowledgement of Act and regulations.* A copy of the Act and regulations shall be supplied to the applicant at the time the applicant is given a license application. The applicant shall sign a receipt at the time of the prelicensing inspection acknowledging that the applicant has received a copy of the Act and regulations, that the applicant understands them, and agrees to comply with the Act and regulations.

(c) *Demonstration of compliance with the regulations.*

(1) Prior to licensing, each applicant shall demonstrate during an inspection of his premises, facilities, and equipment that his facilities and equipment to be used in the treatment of garbage comply with these regulations. If the applicant's facilities and equipment do not meet the standards established by the regulations, the applicant shall not be licensed and shall be advised of the deficiencies and the measures that must be taken to comply with the regulations.

(2) The licensee shall make his premises, facilities, and equipment available during normal business hours for inspections by an authorized representative of the Secretary to determine continuing compliance with the Act and regulations.

(3) The facilities and equipment of an applicant for a license shall be in compliance with all applicable governmental environmental regulations before the applicant will be licensed.

(d) *Issuance of license.* A license will be issued to an applicant when the requirements of paragraphs (a), (b), and (c) of this section have been met, provided that such facility is not located in a State which prohibits the feeding of garbage to swine; and further, that if the Deputy Administrator has reason to believe that the applicant for a Federal license is unfit to engage in the activity for which application has been made by reason of the fact that the applicant is engaging in or has, in the past, engaged in any activity in apparent violation of the Act or the regulations which has not been the subject of an administrative proceeding under the Act, an administrative proceeding shall be promptly instituted in which the applicant will be afforded an opportunity for a hearing in accordance with the rules of practice under the Act, for the purpose of giving the applicant an opportunity to show cause why the application for license should not be denied. In the event it is determined that the application should be denied, the applicant shall be precluded from reapplying for a license for 1 (one) year from the date of the order denying the application.

(Approved by the Office of Management and Budget under control number 0579-0065)

(Sec. 511, Pub. L. 96-592, 94 Stat. 3451 (7 U.S.C. 3802); secs. 4, 5, 9, 10, 12, Pub. L. 96-468, 94 Stat. 2229-2233 (7 U.S.C. 3803, 3804, 3808, 3809, 3811) 7 CFR 2.17, 2.51, and 371.2(d))

[47 FR 49945, Nov. 3, 1982, as amended at 48 FR 57474, Dec. 30, 1983; 49 FR 14497, Apr. 12, 1984]

§ 166.11 Suspension and revocation of licenses.

(a) *Suspension or revocation after notice.* In addition to the imposition of civil penalties and the issuance of cease and desist orders under the Act, the license of any facility may be suspended or revoked for any violation of the Act or the regulations in this part. Before such action is taken, the licensee of the facility will be informed in writing of the reasons for the proposed action and, upon request, shall be afforded an opportunity for a hearing with respect to the merits or validity of such action, in accordance with rules of practice which shall be adopted for the proceeding.

(b) *Summary suspension.* If the Deputy Administrator has reason to believe that any Federal licensee has not complied or is not complying with any provisions of the Act or regulations in this part and he deems such action necessary in order to protect the public health, interest, or safety, the Deputy Administrator may summarily suspend the license of such persons pending a final determination in formal proceedings and any judicial review thereof, effective upon verbal or written notice of such suspension and the reasons therefor. In the event of verbal notification, written confirmation shall follow as soon as circumstances permit. This summary suspension shall continue in effect pending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Deputy Administrator.

(c) The license of a person shall be automatically revoked, without action of the Deputy Administrator, upon the final effective date of the second criminal conviction of such person, as is stated in section 5(c) of the Act. The licensee will be notified in writing of such revocation by the Area Veterinarian in Charge or, in States having primary enforcement responsibility, by the State animal health official.

(d) Any person whose license has been suspended or revoked for any reason shall not be licensed in his own name or in any other manner, nor shall any of his employees be licensed for the purpose of operating the facility owned or operated by said licensee while the order of suspension or revocation is in effect. Any person whose license has been revoked shall not be eligible to apply for a new license for a period of 1 (one) year from the effective date of such revocation. Any person who desires the reinstatement of a license that has been revoked must follow the procedure for new licensees set forth in § 166.10.

166.12 Licensee responsibilities.

(a) A licensed facility shall be subject to inspections. Each inspector will be furnished with an official badge or identification card, either of which shall be sufficient identification to entitle access during normal business hours to the facility for the purposes of inspection. At such time the inspector is duly authorized to:

(1) Inspect the facility, including cooker function;

(2) Take samples of garbage;

(3) Observe and physically inspect the health status of all species of animals on the premises;

(4) Review records and make copies of such records; and

(5) Take photographs. A copy of each photograph will be provided to the licensee within 14 days.

(b) A licensee shall notify an inspector immediately upon detection of illness or death not normally associated with the licensee's operation in any animal species on the licensee's premises.

(c) A licensee shall notify an inspector or the State animal health official or the Area Veterinarian in Charge, as appropriate, of any change in the name, address, management or substantial control or ownership of his business or operation within 30 (thirty) days after making such change.

(d) A licensee shall supply, upon request by an authorized representative of the Department, information concerning sources of garbage. Such information shall include the dates of supply and the names and addresses of the person and/or organization from which the garbage was received.

(Approved by the Office of Management and Budget under control number 0579-0065)

[47 FR 49945, Nov. 3, 1982, as amended at 48 FR 57474, Dec. 30, 1983]

§ 166.13 Cleaning and disinfecting.

(a) *Disinfectants to be used.* Disinfection required under the regulations in this Part shall be performed with one of the following:

(1) a permitted brand of sodium orthophenylphenate that is used in accordance with directions on the Environmental Protection Agency (EPA) approved label.

(2) a permitted cresylic disinfectant that is used in accordance with directions on the EPA-approved label, provided such disinfectant also meets the requirements set forth in §§ 71.10(b) and 71.11 of Title 9, Code of Federal Regulations.

(3) distinfectants which are registered under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135 *et seq.*), with tuberculocidal claims and labeled as efficacious against any species within the viral genus *Herpes*, that are used for purposes of this Part in accordance with directions on the EPA-approved label.

(b) All premises at which garbage has been fed to swine in violation of the Act or regulations in this part shall, prior to continued use for swine feeding purposes, be cleaned and disinfected under the supervision of an inspector or an accredited veterinarian as follows: Empty all troughs and other feeding and watering appliances, remove all litter, garbage, manure, and other organic material from the floors, posts, or other parts of such equipment, and handle such litter, garbage, manure, and other organic material in such manner as not to allow animal contact with such material; clean all surfaces with water and detergent and saturate the entire surface of the equipment, fencing, troughs, chutes, floors, walls, and all other parts of the facilities, with a disinfectant prescribed in § 166.13(a). An exemption to the requirements of this paragraph may be given by the Deputy Administrator or, in States with primary enforcement responsibility, by the State Animal Health Official, when it is determined that a threat to the swine industry does not exist.

(c) Any vehicle or other means of conveyance and its associated equipment which has been used by the licensee to move garbage, except any vehicle or other means of conveyance which also has been used to treat the garbage so moved, shall, prior to use for livestock-related or treated garbage hauling purposes, be cleaned and disinfected as follows; Remove all litter, garbage, manure, and other organic material from all portions of each means of conveyance, including all ledges and framework inside and outside, and handle such litter, garbage, manure, and other organic material in such manner as not to allow animal contact with such material; clean the interior and the exterior of such vehicle or other means of conveyance and its associated equipment with water and detergent; and saturate the entire interior surface, including all doors, endgates, portable chutes, and similar equipment with a disinfectant prescribed in § 166.13(a).

(d) The owner of such facilities and vehicles shall be responsible for cleaning and disinfecting as required under this section, and the cleaning and disinfecting shall be done without expense to the Department of Agriculture.

§ 166.14 State status.

(a) The following States prohibit the feeding of garbage to swine: Alabama, Delaware, Georgia, Idaho, Illinois, Iowa, Louisiana, Maryland, Mississippi, Nebraska, New York, South Carolina, South Dakota, Tennessee, Virginia, and Wisconsin.

(b) The following States and Puerto Rico permit the feeding of treated garbage to swine: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Hawaii, Indiana, Kansas, Kentucky, Main, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, Texas, Utah, Vermont, Washington, West Virginia, and Wyoming.

(c) The following States have primary enforcement responsibilities under the Act: Alabama, Arizona, California, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Michigan, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, and Wisconsin.

(d) The following States issue licenses under cooperative agreements with the Animal and Plant Health Inspection Service, USDA, but do not have primary enforcement responsibility under the Act: Alaska, Minnesota, Washington, and Puerto Rico.

(e) the public may contact the Area Veterinarian in Charge, Veterinary Services, Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agiculture (USDA) or State animal health official (usually the State Veterinarian), or the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Room 870, 6505 Belcrest Road, Hyattsville, Maryland 20782, concerning the feeding of garbage to swine.

[47 FR 49945, Nov. 3, 1982, as amended at 47 FR 58218, Dec. 30, 1982; 48 FR 6090, Feb. 10, 1983; 48 FR 48643, Oct. 20, 1983; 50 FR 18633, May 2, 1985; 50 FR 30415, July 26, 1985]

PART 167—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE SWINE HEALTH PROTECTION ACT

Subpart A—General

Sec.

167.1 Scope and applicability of rules of practice.

Subpart B—Supplemental Rules of Practice

167.10 Stipulations.

AUTHORITY: Sec. 5, 94 Stat. 2230; sec. 6, 94 Stat. 2231; sec. 12, 94 Stat. 2233; 7 U.S.C. 3804, 3805, 3811; 7 CFR 2.17, 2.51, 371.2(d).

SOURCE: 48 FR 30095, June 30, 1983, unless otherwise noted.

Subpart A—General

§ 167.1 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the Department of Agriculture promulgated in Subpart H of Part 1, Subtitle A, Title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings under sections 5 and 6 of the Swine Health Protection Act (7 U.S.C. 3804, 3805). In addition, the Supplemental Rules of Practice set forth in Subpart B of this part shall be applicable to such proceedings.

Subpart B—Supplemental Rules of Practice

§ 167.10 Stipulations.

(a) At any time prior to the issuance of a complaint seeking a civil penalty under the Act, the Administrator, in his discretion, may enter into a stipulation with any person in which:

(1) The Administrator or the Administrator's delegate gives notice of an apparent violation of the Act, or the regulations issued thereunder, by such person and affords such person an opportunity for a hearing regarding the matter as provided by the Act;

(2) Such person expressly waives hearing and agrees to a specified order which may include an agreement to pay a specified penalty within a designated time; and

(3) The Administrator agrees to accept the order in settlement of the particular matter conditioned upon timely payment of the penalty if the order includes an agreement to pay a penalty.

(b) If the order includes an agreement to pay a penalty and the penalty is not paid within the time designated in such a stipulation, the amount of the penalty shall not be relevant in any respect to the penalty which may be assessed after issuance of a complaint.

PARTS 168-199—[RESERVED]

Tennessee, Texas, Utah, Virginia, West Virginia and Wisconsin.

[illegible] Veterinarian in Charge, Veterinary Services, Animal and Plant Health Inspection Service, [illegible] Department of Agriculture (USDA) [illegible] State animal health official [illegible] Department of Agriculture, Animal and Plant Health Inspection Service [illegible]

[illegible]

PART 167—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE SWINE HEALTH PROTECTION ACT

Subpart A—General

§ 167.1 [illegible]

[illegible]

contained in subpart H of Part 1, Subtitle A, Title 7, Code of Federal Regulations [illegible]

Subpart B—Supplemental Rules of Practice

§ 167.11 Stipulations.

[illegible]

penalty.

[illegible] penalty [illegible]

PARTS 168–199 [RESERVED]

FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the CFR Index and Finding Aids volume to the Code of Federal Regulations which is published separately and revised annually.

Material Approved for Incorporation by Reference
Table of CFR Titles and Chapters
Alphabetical List of Agencies Appearing in the CFR
List of CFR Sections Affected

Material Approved for Incorporation by Reference

The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 CFR Part 51 the incorporation by reference of the following publications. For more information on incorporation by reference, see the preliminary pages of this volume.

9 CFR CHAPTER I (PARTS 1–199)
ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

	9 CFR
Agriculture Department	
Veterinary Services, Animal and Plant Health Inspection Service, USDA, Federal Bldg., Hyattsville, MD 20782.	
Uniform Methods & Rules—Bovine Tuberculosis Eradication (Mar. 1980 Ed.).	77.1; 77.4; 77.5
World Health Organization	
World Health Organization, Distribution and Sales Service, 1211 Geneva 27, Switzerland	
United Nations Book Shop, New York, NY 10017	
Laboratory Techniques in Rabies, Third Ed. (1973) Edited by Martin M. Kaplan and Hilary Kaprowski.	113.129

Material Approved for Incorporation by Reference

The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 CFR Part 51 the incorporation by reference of the following publications. For more information on incorporation by reference, see the preliminary pages of this volume.

9 CFR CHAPTER I (PARTS 1-199)
ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

9 CFR

Agriculture Department
Veterinary Services, Animal and Plant Health Inspection Service,
USDA, Federal Bldg., Hyattsville, MD 20782.

Uniform Methods & Rules—Bovine Tuberculosis Eradication (Mar., 1989) 77.1; 77.4; 77.6; 77.8

World Health Organization
World Health Organization Distribution and Sales Service, 1211
Geneva 27, Switzerland;
United Nations Book Shop, New York, NY 10017

Laboratory Techniques in Rabies, Third Ed. (1973) edited by Martin M. Kaplan and Hilary Koprowski. 113.209

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V	Agricultural Research Service, Department of Agriculture (Parts 500-599)
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List of CFR Sections Affected

All changes in this volume of the Code of Federal Regulations which were made by documents published in the FEDERAL REGISTER since January 1, 1973, are enumerated in the following list. Entries indicate the nature of the changes effected. Page numbers refer to Federal Register pages. The user should consult the entries for chapters and parts as well as sections for revisions.

For the period before January 1, 1973, see the "List of CFR Sections Affected, 1949-1963 and 1964-1972," published in three separate volumes.

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12 Added 10797
56.4 Revised 16842
71.1 (h) removed 18011
71.3 (d)(1) amended 18457
71.18 (a)(1)(i)(*d*) and (ii) amended 18011
  Revised 22768
72.5 (i) revised; (j) added 18541
  (a), (c), (f), and (h) revised; (g) amended 19212
  (c) and (i) amended 34860
72.6 Amended 18011
72.13 (b)(2) revised 19012
72.22 Revised 21996
72.23 Revised 21996
72.24 Revised 21996
73.1a (c) revised 2679, 5624, 12801, 18234, 24347, 26904
  (b) revised 6666
  (a) and (c) revised 9007
  (a) revised 9660, 10803, 14156, 15620
  (a) revised; (c) removed 30735
  Revised 32575, 32783, 32915
73.1b Added 31671
73.2 (c)(2) removed 18011
73.5 Amended 18011
  (b) removed 10252
73.9 Removed 18011
73.11 Revised 21996
74 Undesignated center headings amended 18011
  Undesignated subpart headings revised 21996

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74.9 Introductory text and (c) amended 18011
74.12 Heading and (a) amended 18011
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74.18 (c) amended 18011
74.22 (a), (b), (c), and (d) amended 18011
74.23 Revised 18011
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75 Heading revised 20441
75.4 Center heading and new section added 20441
76.2 Amended 849, 1116, 1117, 1577, 1578, 1922, 2441, 2960, 3309, 3397, 4314, 4383, 4937-4939, 5455, 6167, 7318, 7982, 12202, 15363, 17713, 18542, 21173, 33456
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77.6 Amended 18012
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77.8 Introductory text amended 18012
78 Subpart D heading amended 18012
78.1 (k) removed 18012
78.5 Introductory text amended 18012
78.12 (a), (b)(1), and (d) amended 18012
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